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APPROVAL PAGE

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"KNOWLEDGE AND USE OF DIETARY SUPPLEMENTS IN WOMEN OF CHILDBEARING AGE"

By

Teri J. Russell

A Thesis Submitted to
the Faculty of The Graduate School at
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CHAPTER I

INTRODUCTION

The prevalence of dietary supplement use in the United States is profound. In 1994, the Food and Drug Administration (FDA) reported that an estimated 50 percent of the population regularly used vitamins, minerals, or botanicals as a means to improve nutrition (1). A recent article, however, in an issue of US News & World Report (dated 12 February 2001) reported 63 percent of consumers had used a dietary supplement (2).

Over the past decade an increased public interest in maintaining good health and preventing chronic disease, and changes in legislation surrounding the marketing and labeling of dietary supplements, has made the supplement industry one of the most lucrative businesses in the health care market today. According to the Nutrition Business Journal (San Diego, CA), Americans spent a record high of $16.8 billion dollars on dietary supplements in 2000, compared to $13.7 billion in 1997. In this same year, herbs/botanicals and vitamins accounted for 60 percent of the total market sales for nutrition products (3). The number and variety of dietary supplements available to consumers is estimated at 29,000 and growing (4). Herbs and botanicals represent one of the fastest growing segments of the supplement industry as evidenced by a 380% growth in sales from 1990 to 1997 (5). Herbal medicine is considered one of the most common forms of alternative medicines in use today (5).

Several research studies and surveys conducted over the past twenty-five years have attempted to identify basic characteristics of individuals who use dietary supplements. As a result, a familiar pattern has emerged: supplement users are more likely to be female, white, middle-aged or older, have acquired an education beyond high school, and have a higher disposable income (6-12). Frequent use of dietary supplements also tends to be more evident in the western part of the U.S. (7, 12-14). Positive health and lifestyle practices appear to influence dietary supplement use as well. Individuals, who exercise regularly, maintain a lower body mass index, are non-smokers, use alcohol in moderation, and consume diets high in fruits and vegetables are shown to have a higher likelihood of supplement use (15-17). Self-reports of general health by users tend to be rated as good to excellent (7,9,18). In addition, a perception of having control over one's own health is associated with increased supplement use (14, 18). Although the relationship between dietary supplements and chronic disease has not been fully explored, studies have shown that individuals who are diagnosed or perceived to be at risk of developing a chronic disease tend to be regular users of supplements (11,19).

Research studies have identified a number of reported reasons for using supplements. Some of the more frequent ones include: compensation for an inadequate diet, enhanced energy, performance enhancement, and prevention of illness (9,20-23). For many people, the use of dietary supplements is based on a belief that the product will be able to treat a particular disease or reduce the susceptibility to a chronic health problem (10, 21,24).

Much of the research conducted to date on dietary supplements has focused on socio-demographic and lifestyle characteristics, and the relationship between dietary supplement use and nutrient intake. In 1994, Congress enacted the Dietary Supplement Health and Education Act (DSHEA). A primary goal of DSHEA was to maintain consumer access to safe dietary supplements and to provide accurate information on products (1). The Commission on Dietary Supplement Labels was tasked to "evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers" to enable informed choices regarding dietary supplement selection (1,25). In addition, a new dietary supplement label was launched in 1999 in an effort to give consumers clear and understandable information on products and claims. To date there is little known published research that has investigated the decision making processes (strategies) used by consumers in purchasing dietary supplements; also, little information is available on consumers' knowledge and comprehension of the information on supplement labels and issues surrounding safety and efficacy. Because women are frequent users of dietary supplements (6-12), women of childbearing age were the focus population for this research. This population also tends to consume dietary intakes less than 50 percent of the Recommended Dietary Allowances for some nutrients (26).

Therefore, the purpose of this study was to:

1. Explore the decision-making processes used in dietary supplement selection;
2. Assess consumer knowledge and comprehension of the supplement label.

Further, it is important we attempt to identify the education needs of the audience in order to develop materials to increase consumer knowledge of dietary supplements and

promote a level of understanding, which will enable them to make better decisions with respect to dietary supplement selection.

CHAPTER II

REVIEW OF LITERATURE

Background Information on Dietary Supplements

Laws exercising authority over the use of dietary supplements date back to the early 1900's with the enactment of the Federal Food, Drug and Cosmetic Act of 1938 (FDCA) (1). The establishment of this basic law gave the Food and Drug Administration (FDA) administrative control over the safety and labeling issues related to dietary supplements. Since 1938, revisions and amendments to FDCA have led to shifts in the amount of control bestowed to FDA and the basic content of subsequent laws governing dietary supplements. In response to abusive marketing practices by food and dietary supplement manufacturers, Congress passed the Nutrition Labeling and Education Act (NLEA) in 1990 (1). This law gave FDA authority to regulate dietary supplements (known as food supplements at that time) as drugs or food additives. Nutrition labels on foods and dietary supplements were required to provide specific information on the amount and type of nutrients included in products. This piece of legislation also allowed manufacturers to make a health claim linking a specific nutrient in a product to a disease as long as FDA pre-approved the claim (based on acceptable scientific evidence) (1).

In 1994, however, Congress changed the regulatory history of dietary supplements with enactment of the Dietary Supplement Health and Education Act (DSHEA) (1,25). An intense debate brought on by the public and the dietary supplement

industry in response to proposed changes to regulations by FDA (over safety concerns) and worry associated with the availability of dietary supplements is believed to have been the stimulus behind the passage of the DSHEA (1). An amendment to FDCA, this new law not only significantly impacted the labeling and marketing of dietary supplements, but also changed the rules surrounding how supplements are regulated. Prior to enactment of the DSHEA, dietary supplements fell under the same regulatory umbrella as food additives and drugs, requiring pre-market approval and safety testing by FDA before being marketed (1,27). Under DSHEA, FDA's authority over dietary supplements was significantly curtailed; dietary supplements were established as a subcategory of foods exempting them from many of the previous rules of NLEA (1,27). FDA's primary role was now turned to providing oversight regarding safety and manufacturing practices for dietary supplements, and ensuring truthfulness of product information, i.e., product claims, package inserts, and accompanying literature (28,29). For many people, DSHEA was looked on as a resounding success; for others, it was a sign of trouble ahead. See Table 1 for a listing of the major provisions of the DSHEA (1).

Definition of Dietary Supplements

Dietary supplements, by law, are defined as: a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (a) a vitamin; (b) a mineral; (c); an herb or other botanical; (d) an amino acid; (e) a dietary supplement used by man to supplement the diet by increasing the total dietary intake; or (f) a concentrate, metabolite, constituent, extract, or a combination of any of the previously listed ingredients (1,25,30). Examples of the latter

category include creatine, pyruvate, DHEA, lecithin, choline, and glucosamine. Dietary supplements are intended for ingestion in the form of a tablet, capsule, powder, softgel, gelcap, or liquid. Products marketed as dietary supplements have to display the label "dietary supplement" and cannot be represented for use as a conventional food or as a sole item of a meal or of the diet (30).

Table 1: Major provisions of The Dietary Supplement Health and Education Act (1,27)

- First ever inclusion of a "dietary supplement" definition by law
- Responsibility placed on manufacturers for ensuring safety of dietary supplements
- FDA maintains "burden of proof" in finding a product unsafe
- Outlined acceptable statements of nutrition support and health benefits on products
- Authorizes FDA to develop and enforce "good manufacturing practices"
- Specified guidelines for dietary supplement labels
- Gives guidance on how third party literature may be used in dietary supplement sales
- Created a Presidential Commission on Dietary Supplement Labels and an Office of Dietary Supplements (ODS) to provide recommendations and promote research

DSHEA literally opened the door for manufacturers of dietary supplements. Almost any item that met the definition of a "dietary supplement" by law could be labeled as such. As a result, the market for dietary supplements skyrocketed. Today consumers not only have access to an increased number of products but also a multitude of formulations (one of the goals in passing DSHEA). Dietary supplements are available for purchase today through a number of different channels: grocery stores, pharmacies, mass retail (e.g., Wal-Mart, K-Mart), health food stores, and through mail catalogs, infomercials, magazines, and the Internet.

Dietary supplements are marketed with claims purported to provide a number of health benefits to consumers. These so-called benefits range anywhere from correcting a nutrient deficiency to improving memory to enhancing physical performance. In fact, consumers can find dietary supplements today for just about anything. The definition of a dietary supplement as is, is very broad, and as a result, it has become increasingly difficult to distinguish between supplements and drugs (31). Several dietary supplements contain ingredients that have properties and effects similar to prescription medicines (e.g., ephedra, cholestin, and valerian) (31). In addition, items may be marketed as dietary supplements that provide a general health benefit not directly related to nutrition. A good example of this is the hormone, melatonin, often promoted as a sleep aid (31).

Dietary Supplement Claims

Under the current law as described by DSHEA and NLEA, manufacturers are able to use three types of claims in the marketing of dietary supplements (1,27-30). Each claim is unique with its own set of regulatory guidelines. The first type of claim is a "health claim" which allows a statement that "characterizes a relationship between a nutrient or food component and a specific disease or health-related condition" (28-30). This claim is also referred to as a "disease claim." Health claims for dietary supplements are regulated the same as health claims for conventional foods. Manufacturers can use a health claim on a supplement provided it meets the criteria established by NLEA and FDA regulations. A health claim is currently permitted if it has pre-market authorization by FDA based on "available scientific evidence" and "significant scientific agreement" by experts to support the claim (27-29,30). Authorization for a health claim can also be

obtained through the Food and Drug Administration Modernization Act of 1997 (FDAMA). Through FDAMA claims are allowed to be used without FDA approval, granted the claim is based on "an authoritative statement of a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition" (27-29,33). Examples of official scientific bodies include the National Institutes of Health, Centers for Disease Control, and/or the National Academy of Sciences (27-29,33). Manufacturers have to submit to FDA at least 120 days prior to interstate commerce: 1) a notice of the claim; 2) a copy of the authoritative statement relied upon; and 3) a balanced presentation of the scientific literature relating to the health claim. In addition, the product may not be misbranded and the claim must accurately reflect the authoritative statement (27-29,33). Health claims typically represent, in effect, the impact of a specific nutrient in reducing the risk of a disease. Previously authorized health claims by FDA include statements describing the relationship between calcium and a reduced risk of osteoporosis and folic acid and the diminished risk for neural tube defects (27,28).

The second type of claim and the most controversial of all three is the "nutrition support" claim (1,25,27,31,33). An amendment to NLEA (section 6 of DSHEA) permits manufacturers to use "statements of nutrition support" in the labeling of dietary supplements without prior approval of FDA. Acceptable statements of nutritional support include (28,33):

1. A statement of the benefit gained from taking a nutrient (in the case of a classical nutrient deficiency disease), and disclosure of the prevalence of the disease in the U.S.;
2. A statement that describes the effect of a nutrient or dietary ingredient on the structure or function of the human body;
3. A statement that characterizes the documented mechanism by which a nutrient or dietary ingredient maintains such structure or function; and
4. A statement that describes the effect achieved on a person's well being by consuming a specific nutrient or dietary ingredient.

Claims 2 and 3 are often referred to as "structure/function" claims. Examples of nutritional support claims include "for enhanced energy and endurance," "improves mental alertness," and "supports emotional well-being." To make a nutrition support claim a manufacturer must have verification on hand that the statement is truthful and not misleading (based on the review and interpretation of scientific literature) (1,25,27-28,31,33). Information supporting the claim is not required to be sent to FDA or to be provided to the general public. The company must submit notification to FDA of the use of the claim no later than 30 days after the product is first marketed and the supplement label must display the disclaimer, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" (27-29,33). Any claims that make a disease related drug claim are not allowed under current law and as such are subject to the same regulations of a drug or an over-the-counter medication. Because of a concern over structure/function claims being

more in line with drug claims, FDA proposed a set of rules to distinguish between the two distinct claims (27,29-31,33). Table 2 provides a summary of the FDA rules.

Table 2: FDA rules distinguishing disease claims from structure/function claims (27,30-31)

As follows, structure/function claims cannot "implicitly or explicitly" claim:

- an effect on a specific disease or class of diseases
- an effect on "signs or symptoms recognized by health care professionals or consumers as characteristic of a specific disease"
- an effect on a "consequence of a natural state that presents a characteristic set of signs or symptoms" recognized by the medical profession or consumers as an abnormality of the body or that associated with aging
- an effect on a disease through the use of names or formulations similar to prescription medications or disease conditions, i.e., use of the term "disease" or "diseased"
- a product belongs to a class of products intended to diagnose, treat, mitigate, cure, or prevent disease (e.g., antibiotic, diuretic)
- a product has the same effect "as that of a recognized drug or disease therapy"
- a product is used to augment a particular therapy or drug action
- a product plays a role in the body's defense or response to a disease
- a product treats, prevents, or mitigates adverse effects associated with a medical therapy

The third claim is a "nutrient content" claim. This is a claim that "expressly or implicitly characterizes the level of a nutrient" (28,33). FDA has authorized certain nutrient content claims for substances in which there is an established "Daily Value" (DV) or a Reference Daily Intake (RDI). For example, a product's label may be able to specify or claim the supplement is "high in" or an "excellent source of" if the supplement provides 20 percent or more of the DV or RDI for a said substance in the amount commonly consumed (28,33). Nutrient content claims fall under the same regulatory guidelines as health claims.

Safety, Efficacy, and Quality Control

Federal law requires manufacturers of dietary supplements to be responsible for ensuring the products they place on the market are safe under conditions of use described on the label; if no conditions are listed, then the law applies to ordinary conditions of use (1,28). FDA is not required to test any dietary supplement with ingredients present in the food supply prior to 15 October 1994, with an established history of use, or other evidence that the product "can be reasonably expected to be safe" under the specified conditions of use on the label (1,28,30). Manufacturers introducing a "new ingredient" (marketed after 15 October 1994) must either (1, 28-29,30-31):

1. Submit to FDA (at least 75 days prior to its expected entry on the market) information that the dietary supplement containing the new ingredient does not present an unreasonable or significant risk of illness or injury to the public under described conditions of use; or
2. Petition FDA to establish conditions under which the new ingredient would be expected to be safe according to directions for use.

The rapid influx of new dietary supplements on the market compounded with a less than ideal regulatory environment poses a significant risk to consumers in the area of compromised quality control and related issues of safety and efficacy in using dietary supplements. Unlike drugs and food additives that must demonstrate proof of safety and efficacy prior to being available to the public, dietary supplements do not have to adhere to the same standards. Current legislation provides no measures for testing of products for effectiveness, no standards for evaluation of safety, and no requirements for review of

purported health claims. As a result, consumers have no guarantee a product will perform as expected and, most importantly, will pose no risk or harm to personal health; individual's well being are literally left to the entrusted good will of manufacturers and the supplement industry.

One of the provisions of DSHEA is the "burden of proof" or authority given to FDA to show that a dietary supplement is unsafe for public use (1,28,31). FDA does not have to show an injury has occurred, only that there is a reasonable possibility of harm with use of a product (1). Once a product is marketed, the agency has the authority to enforce and restrict its sale if it has determined the product presents a "significant and unreasonable risk of illness or injury" under conditions of use recommended on the supplement label. A prime example of this occurred in 1997 when FDA proposed to limit the amount of ephedrine alkaloids in dietary supplements and issued warnings to consumers about the hazards associated with the use of such products following several reported adverse events (28). Once an adverse event or product is identified, FDA has a series of measures it can take to limit market access to the product (29,32). FDA can mandate labeling changes, require warnings to be placed on product packages, issue medical and safety alerts, and initiate recalls and/or a withdrawal of the product from market (29,32). DSHEA also provides the Secretary of Health and Human Services authorization to remove a product from sale should it pose a risk to public health and safety (1, 25). Individual states may also take action to restrict potentially harmful substances as evidenced by the state of Florida taking action to ban all sales of products containing ephedra (28).

It can be said that dietary supplements have been shown to offer both positive benefits to health as well as proven risks. For years, the underlying theme of much of the nutrition advice given to the general public was one which stressed the importance of consuming a wide variety of foods to meet daily nutrient requirements. Individuals were discouraged from using supplements other than a basic multivitamin. Today, however, the philosophy has changed to a more liberal one. In fact, the position statement of the American Dietetic Association (2001) and more recently the published Dietary Guidelines for Americans (5th Edition) recognize that there may be some situations in which dietary supplements are warranted to meet specific nutrient needs (34-35). Dietary supplements should not replace a well balanced diet; however, they may "fill in the gaps" for nutrients that may not be easily obtained through food sources (29). Dietary supplements can "play an important role in preventing disease and promoting good health" (29). For instance, the role of calcium in reducing the risk of osteoporosis is well-recognized (21,36). Clinical studies have shown that folic acid when taken in adequate amounts through supplementation during pre-conception and early pregnancy significantly decreases the risk of neural tube defects (21,36). In addition, an increase in the amount of folic acid obtained through fortified foods and/or supplementation has been shown to reduce the blood levels of homocysteine, a clinical marker associated with increased risk for heart disease (36-37). Epidemiological evidence strongly suggests Vitamin E may play a role in reducing the risk of heart disease as well (21,36,38).

Scientific evidence that supports the use of herbals in preventing disease and promoting good health is not as well known or understood. In many other countries, herbs and botanical are commonly used and prescribed as a form of medical therapy (39). Much of the research that has been conducted on herbs has been done in Europe and Asia. In Germany, the German Commission E regulates herbals as drugs. This panel reviews and approves products for safety and efficacy based on historical and scientific evidence (36,39). It should be noted, however, that studies in Germany that have demonstrated efficacy with herbs were based on standards that were set lower than those for conventional medicines (40). The *Physician's and Pharmacist's Guide to The Top 10 Scientifically Proven Natural Products* provides a good review (with references) of several animal and human studies demonstrating efficacy for some of the more commonly used herbals/botanicals in Europe. Examples include bilberry (vision and circulation), ginger (nausea and vomiting), gingko biloba (cognitive function), milk thistle (liver disorders), and valerian root (sleep disorders and anxiety) (39). In the United States, however, herbals have not undergone extensive testing to support the purported benefits they claim to provide; much of the published research is incomplete and/or inconclusive and benefits may be based instead on a long history of traditional use rather than scientific evidence. Because herbals are not patented in the U.S., there is no incentive for companies to test these products for safety and efficacy. In short, the money ($ millions) and time (an estimated 12 years) required for drug approval is a deterrent (41-42). Therefore, many manufacturers elect instead to market a product as a dietary supplement with claims that are suggestive of a drug effect. A recent clinical trial,

however, in the U.S. showed gingko biloba may be effective in stabilizing or slightly improving symptoms associated with Alzheimer's disease (36,43-44). In addition, results of placebo-controlled studies indicate that saw palmetto may be beneficial in improving symptoms related to benign prostate hyperplasia (29,39,44). For supplements, such as echinacea, ginseng (mostly animal studies), beta carotene, and glucosamine/chondroitin, results of studies thus far point to some health benefits; however, long term, prospective controlled human studies are needed before a definitive answer can be given regarding efficacy (36,44-45). The National Center for Complimentary and Alternative Medicine through the National Institutes of Health has started clinical trials for St. Johns wort (depression), gingko biloba (memory), saw palmetto (benign prostate hyperplasia), and glucosamine/chondroitin (osteoarthritis) (46). Plans have also been announced to commence studies next year for ephedra (weight loss) (2).

There are a number of potential health risks and concerns related to dietary supplement use. Between January 1993 and October 1998, FDA received 2,621 reports of serious health problems or adverse events related to dietary supplements, including 101 deaths (47). An adverse event is defined as an "incident of illness or injury that may be associated with a product or ingredient"(31). Contrary to drugs, manufacturers are not required to report to FDA any adverse events or side effects associated with dietary supplements. The current adverse event reporting system for dietary supplements is entirely voluntary (i.e., MedWatch, National Network of Poison Control Centers) (32). FDA has reported receiving a total of less than 10 adverse event reports from supplement manufacturers. In addition, only 527 of 2,547 reports between 1994 and 1999 came from

health care professionals (31). A recent FDA commissioned study established the agency receives less than 1 percent of all reports of adverse events associated with dietary supplements (31). Some of the proposed explanatory factors include: 1) the manufacturer not having to report adverse effects; 2) symptoms being similar to other known medical conditions or signs of aging; 3) a long lag time between consumption and actual adverse effects, and 4) not knowing the process on how to report an adverse event or reluctance to do so (1,48). Another reason may be that consumers have the perception that "natural" means the product is safe (30). A study conducted to identify American's views towards dietary supplements found 49 percent of regular users compared to 33 percent of non-users believed dietary supplements are adequately tested for safety; in addition, 53 percent of regular users believed people are rarely or never harmed by using supplements (10). A second study by Eliason et al. found similar belief patterns (49). Participants generally believed "natural" products were safer than pharmaceuticals and individuals were not overly concerned with the safety of the products. And finally many patients fail to inform their primary physicians of their use of dietary supplements as part of their medical history. In 1993, a survey conducted by Eisenberg et al. discovered that 72 percent of patients who used unconventional therapies (including herbals) did not inform their primary physicians (50). In another study, comparing use of dietary supplements and nonprescription medicines as reported on a written medical questionnaire versus verbal recall, more than one half of the patients who took dietary supplements did not report this to their health care provider even though the information was requested (51).

A study looking at patients in a family practice setting, found more than 50 percent of patients used dietary supplements, yet they often failed to discuss the use of these products with their physician (52).

Adverse illnesses and injuries associated with the lack of safety and quality control measures for dietary supplements are varied. Potential problems include the possibility of ingesting contaminated or adulterated products, problems with purity and consistency in manufacturing of ingredients/products, potential interactions between herbals/botanicals and prescription medications, hypersensitivity, and effects of consuming toxic or lethal doses of some nutrients. Many of the medical problems reported from adverse events associated with dietary supplements have included liver damage, kidney disease, high blood pressure, increased bleeding times, central nervous system effects, headaches, nausea, irregular heart rates, and even death (44,47). FDA has issued a report containing a list of dietary supplements that have been associated with adverse events and pose a serious health risk to the public (28,53). The list contains the herbals/nutrients: chapparal, comfrey, germander, willow bark, L-tryptophan, Vitamin A, and ephedra alkaloids. One of the most serious cases involving adverse events linked to a dietary supplement occurred in 1989-1990. More than 1,300 reported cases of eosinophilia myalgia syndrome that resulted in 36 deaths were found to be the result of contamination of an amino acid, L-tryptophan (54). More recently the attention has been shifted to products containing ephedra alkaloids (also called ma huang), widely promoted as a supplement to help with weight loss and enhanced energy. A review in the New England Journal of Medicine reported 140 adverse reports as being "definitely or

probably related" to the use of ephedra alkaloids (55). The most frequent side effect reported was high blood pressure; other symptoms included increased heart rate, palpitations, strokes, seizures, and death. In January 1999, FDA issued a warning to consumers not to purchase products containing gamma butyrolactone (GBL) and asked for a voluntary recall of supplements containing the compound (56). Fifty-five reported cases were linked to GBL (5 involving children less than 18 years of age); side effects included vomiting, reduced heart rates, seizures, and one death (56). In Belgium, during the early 1990's, approximately 10,000 dieters took a weight loss product containing a mix of Chinese herbs and western medications (57). A sub sample of 170 individuals ended up with kidney failure and/or kidney damage as a result of ingesting a diet pill containing a mislabeled herb. A derivative of the herb, Aristolochia fangchi, was used in producing the diet pills rather than the intended herb, Stephania tetranda. Then in 1994, the first cases of urinary tract cancer and pre-cancerous lesions were discovered in 37 of these individuals. This herb recently resurfaced in the United States in May of this year. FDA released a notice to consumers warning of the potential health risks associated with the use of this herb; and reported the voluntary recall of the company, Vital Nutrients, for two of its products containing Aristolochic acid (58). Digitalis lanata toxicity has also been identified in two cases reported by Slifman et al. (59); the herb, plantain, used for internal cleansing was contaminated with cardiac glycosides. And still another adverse event occurred in a case involving a young woman who developed symptoms of hyperthyroidism after ingesting an herbal preparation containing 2-3 times the level of replacement thyroid hormone (60).

Heavy metals including lead, arsenic, and mercury have been found in herbal preparations, particularly those from foreign countries (42,61-62). Ginseng, a popular and frequently consumed herbal in the United States, underwent testing by Consumer Labs, a small independent company that inspects products for quality control. Testing of 21 brands of ginseng identified 8 brands containing a high levels of pesticides and significant amounts of lead (63). In a separate study, looking at over-the-counter ginseng products, a high number of samples contained cadmium, nickel, and lead; in addition, five samples had concentration levels of pesticides above 100ppb (64).

The active ingredient content of many dietary supplements is also in question. Several tests to evaluate the level of active compounds in dietary supplements have been conducted by Consumer Labs. Tests have been run on several brands of ginseng, gingko biloba, saw palmetto, and glucososamine/chondroitin. Results showed many of the products contained either less than or more than the reported level of the active ingredient on the supplement label (41). Researchers at the School of Medicine, University of California-Davis, looked at 25 different ginseng preparations obtained from three local health food stores; findings indicated there was considerable variability in the products tested (66). Eleven out of 25 brands tested contained amounts different from the specified concentration on the label. Five contained more, and six contained less, with a range in concentrations from 10.8 percent to 327.7 percent of the active ingredient on the label. Like any natural substance, there is always a certain level of risk associated with any compound consumed in excess of the recommended or suggested amounts. Known risks have been identified with consumption of high levels of Vitamin A (31,36).

For example, high levels of Vitamin A appear to be teratogenic (66). In a study of 22, 948 pregnant women, 1 out of every 57 births resulted in a neural tube defect among those women who consumed more than 10,000 IU per day of preformed Vitamin A. Other nutrients that appear to cause side effects or interfere with the utilization of other nutrients when consumed in high amounts include the vitamins B6 and D, calcium, iron, and folic acid (36,48). And yet for some substances the amount consumed results in very different effects on the human body. For instance, capsaicin, a major constituent of chili peppers, tends to act as a protective anti-carcinogen when consumed in low or moderate amounts; however, when taken in excess, it appears to promote the development of gastric cancer (67).

The risk for interactions between herbals and prescription medications is potentially quite large and relatively unknown at this time. What we currently know is small in comparison to what needs to be learned with respect to the interactions that can occur as a result of combining prescription and herbal compounds. Results of a survey by Eisenberg et al. (5) indicated approximately 15 million (or 1 in every 5) individuals were taking herbal medicines and/or high dose vitamins while also taking prescription medications.

Another study found 52.2 percent of participants surveyed were combining supplements with prescription medication (9). What was especially alarming about this population was the fact that the average intake of dietary supplements was 5.9 per client. Some of the participants in this study were taking supplements associated with adverse health events and considered high risk. Thus the potential for risk may be high for those

people who tend to consume multiple dietary supplements with or without prescription medication. Herbals including fever few, grape seed extract, and ginkgo biloba contain compounds known as bioflavenoids that appear to inhibit platelet aggregation, increasing the risk for bleeding in patients that may use anticoagulant medications (e.g., warfarin and coumadin) (36,68). High levels of ginseng have been associated with severe headaches, vaginal bleeding, hypoglycemia, as well as altered blood coagulation (44). In February 2000, results were released from a study conducted by the National Institutes of Health that indicated St. Johns wort may negatively interact with antiretroviral drugs (indinavir) by decreasing plasma concentrations (29). In addition, the herb has also been reported to reduce circulating levels of drugs used to reduce the risk of organ transplant rejection (29). Other reported side effects include photosensitivity and possible seratonin syndrome when combined with other drugs that affect seratonin levels (31,36).

There are some safeguards in place to help with the monitoring of quality (mainly safety) issues related to the production of dietary supplements. DSHEA gave FDA the authority to establish "good manufacturing practices" (GMP) for dietary supplements (1,29). These standards were intended to provide oversight to and help manufacturers with the regulation of the preparation, packaging, and holding of supplements under conditions that result in a "safe and properly labeled product;" a guarantee of potency and purity is not usually available (28). Dietary supplement manufacturers currently follow the same GMP's designated for food (29). FDA has proposed GMP's developed by the supplement industry; they are currently pending approval (29).

Dietary supplement manufacturers also have the opportunity to participate in an independent auditing system, "United States Pharmacopoeia" (USP) (29). The USP establishes standards and publishes a national formulary for drugs, excipients, dietary supplements, vitamins, and minerals in terms of product strength, quality, and purity (29,69). For years the USP has been working with vitamins and minerals, and only a few botanicals; this is about to change. In February of 2001 (70), the USP announced plans to begin a pilot program that would "assure the quality of dietary supplements." The program will be a voluntary, national certification program that will allow companies to work with USP to develop standards and procedures for an eventual national program. Companies will be able to use a certification stamp on their products if they comply with the program-a symbol of quality and purity (70). While the stamp will indicate to consumers that the product they are receiving is safe for consumption and contains ingredients in the amount stated, the stamp will not guarantee effectiveness. This new program will lend to further testing of botanicals, an area of research currently weak in the United States.

Dietary Supplement Labeling/Advertising

DSHEA contains a provision that exempts certain literature (third party) from being classified as labeling (1,29). The provision permits manufacturers to supply printed material in the form of an article, book chapter, or scientific journal abstract to the consumer to be used in connection with sales of supplements. Certain criteria apply, however. The information must be: 1) truthful and not misleading; 2) can not promote a particular brand or product; 3) must present a balanced view of the available scientific

literature; 4) be displayed with similar materials; 5) should be physically separated from the dietary supplement; and 6) not have appended to it another promotional item (1,29).

While FDA regulates the content of labels found on product packages and other labeling to include package inserts and other promotional material, the Federal Trade Commission (FTC) regulates claims made in advertising, i.e., internet marketing, magazines, infomercials, television, and other similar mediums (27,71). Both, however, have the same goal at heart-to ensure consumers receive truthful and accurate information about dietary supplements that will enable them to make informed decisions when purchasing supplements (71). Whether printed on a label, or advertised in a magazine, all health claims must be truthful and not misleading to the consumer (71). In 1999, FTC took action against seven companies for violating the regulations for "truthfulness" (28,41). The agency also sent warnings to 1200 web sites for claims on products that crossed the line for purported benefits. More recently action was taken against a company that was promoting a throat spray that would reduce or eliminate snoring and sleep apnea (72). The company agreed to settle charges with FTC based on the fact of "inadequate substantiation."

The first program for nutrition labeling was established in 1973 (1). It was strictly a voluntary program for manufacturers of food products; only food items displaying a claim were mandated to carry a nutrition label (1). The label had to comply with standards and format set by FDA (US RDA format). Dietary supplements were considered exempt since they would be covered by special use regulation (1). In 1990, as a result of an increase in the number of misleading and suspicious claims on food

products, the Nutrition Labeling and Education Act was passed which would require nutrition labeling for all foods and supplements (1). The intent of NLEA was to employ standards for nutrition labeling and provide provisions for permissible claims. FDA was directed to establish an "appropriate" format for labels in an effort to standardize nutrition labeling; the RDI replaced the RDA and the "Nutrition Facts" panel was born (1). Then in 1994 NLEA was amended and the DSHEA was passed specifically addressing dietary supplements. The new law specified that nutrition labeling for dietary supplements would be provided in a manner appropriate for the product and in accordance to FDA regulations. DSHEA approved three departures for dietary supplement labeling from previous nutrition labeling (1). Dietary supplement labels did not have to list any substance(s) not in the product, could include substances without an established daily value (as a percentage), and could include the source of the nutrient or substance (i.e., calcium from calcium citrate). The final rules for the dietary supplement label went into effect March 1999 (See Table 3).

As a piggyback to the "Nutrition Facts" label, the new "Supplement Facts" label contained a similar format and was intended to serve as a useful tool to help consumers make informed decisions regarding their choice of dietary supplements (53). The label was intended to provide additional information to increase consumer knowledge and provide an easy means for comparing products. Unfortunately, little or no information is available to give an indication of whether consumers are in fact making informed choices when selecting dietary supplements. Several studies and surveys, however, have been completed that have addressed consumer understanding and knowledge of the food label,

including the "Nutrition Facts" panel. Reviews of the research applications surrounding the nutrition food label would serve as an adjunct to our understanding of the dietary supplement label. Both labels are similar in format with shared information (serving size, % daily value for established nutrients, active and inactive/other ingredients), and both were intended to be used as a reference to assist consumers in assessing the relative value of available food and dietary products. Something else that should not be overlooked is the fact that consumers who tend to read nutrition labels share similar sociodemographic characteristics as those who use dietary supplements (6-12,73).

Table 3: Final rules for dietary supplement label (March 1999) (29,53)

- Statement of identity-labels must contain the name of the product and display the words "DIETARY SUPPLEMENT" (bold letters) on the front panel.
- The name of each ingredient and quantity (listing of ingredients by the common name in descending order by weight); active ingredients must be listed; other ingredients (e.g., fillers, flavors) must be provided; product may contain a statement "does not contain" as an identifier for individuals with allergies.
- If the product contains a proprietary blend, the total amount of the blend should be indicated on the label.
- For botanicals, the label must contain the part of the plant the ingredient was
- derived from (e.g., root, leaf, flower).
- Serving size (determined by manufacturer)
- Directions for use
- Quantity and percent daily value (DV) for 14 nutrients and any other added vitamins or minerals in significant quantities in product; for items with no established RDI, the amount per serving must be given
- Botanicals and other ingredients with no official recommendations are listed below nutrients in which there are dietary values
- Supplements may carry statement "Standardized" or "USP" or "NF" if product meets requirements for use
- Name and address of manufacturer, packer, or distributor
- The term "high potency" can be used on products containing 100% or more of the established RDI for that vitamin or mineral
- If a "structure/function" claim is made, the FDA disclaimer must be shown
- Labels may also contain warning statements (i.e., risk in pregnancy)

Studies Related to Knowledge of the Nutrition Label

Some of the first studies undertaken to assess comprehension of the nutrition food label were those by Jacoby et al. (74). Two of these earlier studies were conducted in supermarkets using the US RDA label. Individuals were approached in a supermarket by a trained interviewer who asked if they would agree to participate. If they agreed, several questions were then asked regarding usual shopping habits, with specific questions directed towards probing for consumer awareness of use, and comprehension of the food label. Participants in the first study numbered 58 and in the second study, 184. The percentage of participants who stated they were aware the information existed and was available on food products was 79 (study 1) and 82 (study 2) percent. Fifty-five and 57 percent of participants, respectively, claimed they used the food label. Individuals were then queried about their understanding and knowledge of four common nutrient terms: calories, carbohydrates, fats, and protein and asked to give the amount of each in a container of breakfast cereal. No more than 51 percent from both studies could provide the correct answers; although it was interesting that 90 percent in both studies also thought the label was easy to use. When asked about the meaning of each, most were only able to verbalize a vague impression of each; in addition, most were unable to provide recommended amounts that were needed daily in their diet.

Based on these findings, a third study was performed to address basic nutrition knowledge (74). A nineteen-item true/false nutrition quiz was implemented with 172 college undergraduates. Examples of questions included "fats have twice the amount of calories," "vitamins and minerals can not give energy," and "fats and carbohydrates make

up over 80 percent of most diets." The average correct response was a score of 9.88 (out of possible 19), indicating a poor level or understanding of nutrition. Overall results from all studies suggest, that while individuals may claim to understand and use the nutrition label, most do not.

A more recent study using the new "Nutrition Facts" label was conducted by Miller et al. (75) looking at knowledge and use in women with non-insulin dependent diabetes mellitus. This study used three focus groups and individual interviews. Results indicated participants preferred the new nutrition facts label format over the previous one. The participants indicated they thought the new label was easier to use, easier to read and comprehend, and provided relevant information. The majority indicated they almost always used the label when purchasing a product for the first time. Sugars, total fat, and sodium, in that order were the main nutrients used to assess products. Those considered as non-useful included percent daily value (%DV) and total carbohydrates; this was essentially due to confusion and information non-meaningful to the participant. Confusion was related to use of total fat and problems defining the types of fats. Many also felt the "low fat" claim on the front of the cereal box was purely a "gimmick" to entice the customer to buy the product. No one was able to report the criteria necessary for using the "low fat" claim. Knowledge of mathematical operations was also poor; only 2 out of 14 women could calculate the percent of calories from fat or explain the purpose of percent DV. Overall results support the need for quantitative education to increase understanding and ability to use basic concepts of the nutrition label.

Burton et al. (76) looked at how individuals use the information off the nutrition label (Nutrition Facts panel) in a nutrient usage task; specifically, how accuracy affects nutrition evaluations of products, purchase intentions, and the factors related to accurate usage of information. The researchers hypothesized: 1) evaluations of both positive and negative nutrients (unfavorable nutrients more strongly) would be positively related to overall nutrition perceptions of the product and purchase intentions, 2) individuals who can use nutrition information more accurately will have lower evaluations for products with "poor" nutrition value and higher evaluations for those with "good" nutrition value, and 3) accurate nutrition information use is positively related to nutrition knowledge, motivation to process information, ease of understanding of labels, and attitude toward the nutrition facts panel. The study employed a statewide household panel (n=318) who were mailed a mock package (frozen chicken dinner) that included either a "poor" or "good" nutrition value condition (153 poor and 165 good) and a survey containing usage and knowledge measures. Dinner packages were pre-tested to ensure perceived differences between both. Findings showed more than half of participants were able to answer 89 percent or more of usage questions correctly indicating proficiency with use of label information. Results also showed support for motivation, knowledge, and attitude being associated with accuracy; specifically, measures of nutrition knowledge were strongly linked to accuracy. These findings were considered impressive in light of results previous studies by Jacoby et al. and Miller et al. showing poor knowledge and comprehension of information on the nutrition label. (74, 75). The authors note, however, that this study may not be indicative of the results that may be found using an

actual purchase situation, one in which situational and market factors may have a significant influence on decisions at time of purchase.

Two separate studies have focused primarily on comprehension of and the ability to use the percent daily value off of the Nutrition Facts panel. One of the studies included a nutrition education module (77) and the other did not (78). Fuan et al. (77) wanted to explore whether enhanced knowledge and use of the nutrition label would facilitate the effectiveness of the percent daily value. It was hypothesized that more knowledge would lead to more accurate nutritional evaluations; that is, those with greater knowledge would benefit more from the provision of %DV. Participants (205 students) were randomly assigned to a 2 (nutritional value: higher or lower) x 2 (%DV present or absent) x 2 (label knowledge: higher or lower) design. For the last factor, knowledge was manipulated (enhanced) through an induction designed to increase understanding of food labels, including the %DV. Unlike the lower knowledge group, participants in the higher knowledge group were provided with three pages of education materials focused on positive and negative nutrients, concepts of DV and %DV, and how to use the %DV in evaluating a product's healthiness. This preceded the actual tasking of evaluating the healthiness of a product (one of four possible labels) for three of the nutrients manipulated on the label (sodium, fat, and fiber). Individuals who received the knowledge induction showed greater label knowledge than those who did not receive the induction. These same participants were also able to more accurately rate the stronger (weaker) product as more (less) favorable. In the other study (74) the primary focus was on whether consumers understood the %DV and could use the label information to rate a

food as low, medium, or high in fat. Though 41 percent of the 104 participants said they "usually" use food labels, and 49 percent stated they use them "often" or "sometimes," the majority of respondents could not define %DV and did not find it useful in evaluating food labels (similar results to Miller et al.). Most respondents were able to accurately rate the five food categories (bread, beverage, main dish, side dish, and snack) based on fat content. However, there were still some misconceptions, i.e., 5% rated whole milk as low fat, and another 28% stating it was medium fat. Participants overall did better with the bread and side dish. The authors attribute this to the possibility of prior health beliefs about the fat content of certain types of foods rather than information from the food label. Also some individuals may be using other sources of information from the label, i.e., fat grams. A final note from the authors is the fact that the sample was composed mostly of vitamin users, which may have contributed to the results (better-educated, more healthful behaviors, strong association between diet and health).

In recent years, many studies have focused on how consumers' process and use the Nutrition Facts label in the presence or absence of health claims. The results of this research is believed to be valuable and pertinent to the study of dietary supplement label knowledge and use since dietary supplements also contain several claims (nutrition support, nutrient content, or health claims) in addition to the Supplements Facts panel. Results of research conducted by FDA in which focus groups were used, has shown many consumers believe the information found on the Nutrition Facts panel is government sponsored and basically view it as reliable and trustworthy information that can be used to validate claims found on food products (79). Consumers were found to be

highly skeptical of health and nutrition claims; in fact, they were viewed as an attempt by companies/manufacturers to sell more products. The majority of group members were unaware of the regulations that specify when claims can and cannot be used on foods.

Ford and colleagues (80) tested to see if consumers' evaluations of a product's nutritional value would be affected by the presence of a health claim in the presence of nutrition information for the product. They hypothesized: 1) consumers would not be able to understand nutrition information on a food package, and 2) in a situation in which both the nutrition label information and a health claim was available, consumers would weigh the nutrition information in such a way that inferences would likely be made about the product. Examples of suggested effects included: a positivity bias (product provided a better rating due to the presence of a health claim), a halo effect, or magic bullet effect. Findings showed individuals were able to understand the nutrition information given to them. In addition, there was no real effect by the health claim, other than products that included a claim related to cholesterol and heart disease, faired better compared to nutritionally identical products without the claim. The authors warned that the results "might be of concern particularly, if in reality consumers rely solely on health claims and ignore nutrition information altogether."

Keller et al. (81) examined the effect of three different nutrition claims (99% fat free, low in calories, and low in fat) across various levels of products that included a control (no claim made). They specifically wanted to see if these claims would affect the conclusions consumers would draw about the product when the claims are consistent with the information on the nutrition label and when they were not. Additionally, they

assessed the level of motivation consumers displayed when acquiring and/or processing information. And finally, whether consumers overlook nutrient information in the Nutrition Facts (NF) panel, because they focus more selectively on information on fat and saturated fat. It was believed consumers would use an information framework consisting of principles of accessibility (ease with which a piece of information is retrieved from memory or obtained from the immediate environment) and diagnosticity (perceived usefulness of information in making a decision). Though both the NF panel and promotional nutrition claims are readily accessible, the authors believed the NF panel would be viewed as more useful. It was also noted the nutrition label had been part of a nationwide education campaign to increase consumer awareness and knowledge of the label. Results indicated claims did not affect the overall nutrition evaluations of products. When a NF panel is readily available, claims found on the front of the package do not positively influence the consumers' evaluation of the product. Claims that were not consistent with the nutrition label information were a factor in producing lower evaluations of the manufacturer's credibility. Thus, when information from the nutrition label was present, consumers tended to be more selective using this information over claims made on the package front.

Findings from another study by Garretson and Burton (82) in 2000 found outcomes similar to Levy (79), Ford et al. (80), and Keller et al. (81). Again this study looked at how consumers would process and use information from the NF panel in the presence of a health claim or nutrition claim. The investigators looked primarily at the effects of claims and information involving the nutrients, fat and fiber. It was believed

fat would prove to be the more salient and diagnostic of the two and a high amount on the label would lead to less favorable nutrition and brand attitudes and purchase intentions. Differences between a high fat/high fiber and low fat/high fiber nutrition condition would have greater effects than the conditions of low fat/high fiber and low fat/low fiber. Lower levels of fat (and saturated fat) would lead to a lower perceived likelihood of disease risk and differences in fat levels will be perceived as greater than differences in fiber levels. Other hypotheses involved the relationship between nutrients and risk for disease and perceptions of manufacturer credibility in claims in the face of inconsistent NF information. Overall findings indicated that when a nutrient claim is not consistent with the NF info, the credibility of the manufacturer is rated lower than when no claim is made or claims are consistent (similar findings with Keller et al. and Levy). In addition, fat proved to have a strong effect (compared with fiber) on nutrition attitude, and significant effects on both brand and nutrition attitude. Front label claims and fiber information on the nutrition label had little effect on consumers' product evaluations. A question remains, however from this, would the investigators have found the same results when looking at nutrients that are considered less diagnostic and less relevant to product evaluations? Once again, this study did not use an actual in store/retail environment which may have significantly skewed the results or hampered the evaluation process.

One final study that needs to be mentioned found very different results compared with the previous five. Roe et al. (84) recruited 1,043 shoppers from a mall for a face to face interview. Participants were randomly assigned to one of three realistic mock-up products (yogurt, frozen lasagna, and raisin bran cereal). There were ten possible claim

conditions, with one condition serving as a control (no claim), one involving a nutrient content claim only, and eight involving a mix of different health claim formats combined with a nutrient content claim. The question addressed by the study: do consumers rely on claims when evaluating products and making purchase decisions; and if so, how does this effect the nutritional judgement and quality of choice? Respondents were given a single item and provided time to review the package (which remained available through-out the interview) before answering questions related to the perceived healthiness of the product, purchase intention, and health benefits accrued from eating the product. Results were significantly different from the previous described studies. The presence of a health claim (and to a lesser extent a nutrient content claim) was significantly associated with a search limited to the front panel (truncated). Individuals with a lower education level tended to limit their search to the front panel. However, individuals who reported using food labels were less likely to stop their search. Those who looked primarily at only the front panel were also likely to purchase the item. Products with health and nutrient content claims were viewed as healthier. Health claims appeared to cause a "positivity" bias and induced a halo effect. What was especially intriguing about this study was the fact that 56 percent of the participants used dietary supplements. Could it be that the presence of a health claim had a greater attraction value for those individuals who are already likely to be using supplements for a purported health benefit?

With the exception of Roe et al. (83) the majority of studies revealed that consumers tend to rely on and trust more the Nutrition Facts panel (versus the nutrition claims) when providing overall nutrition and product evaluations. Probably one of the

most important underlying messages to come out of several of these studies is the importance of education. Individuals who possessed greater understanding and comprehension of nutrition information provided on food labels displayed greater accuracy and use of the information in evaluating food items (76,77,80).

Jacoby et al. (74) said it best, "placing nutrition information on to a package label, we engage in printing, nothing more...we assume the act is equivalent to communicating with consumer...assume or presuppose that the consumer wants, will acquire, and having acquired will understand and use the information." Thus consumers not only need to be able to obtain the appropriate information off the food label, but they must also be able to understand the information to enable them to effectively use it.

CHAPTER III

THEORETICAL FRAMEWORK

Consumer Information Processing/Consumer Decision-Making

Consumer information processing (CIP) is a well-recognized and utilized model to help understand and explain consumer behavior. The act of making a decision and actually purchasing a product is a key stage identified in CIP.

Decisions vary in complexity and can relate to things other than just the purchase of goods and services (84). Consumers make decisions every day…ranging from the simple decision of what to have for dinner one night to the more complex decision of selecting a new car. Decisions also usually entail a choice or selection between two or more alternatives or behaviors. The purchase of products, however, is the most discussed and researched aspect of consumer decision making. Different variations of the same CIP model have been proposed, but the major concepts can be summarized as: a) information search, b) information processing, c) decision rules, d) consumption and learning, and e) information environment (85).

Information search includes the acquisition and evaluation of information. Basic components include:

- Exposure to information: consumer must first be exposed to information in some way in order for it to have an effect on behavior. An example would include the presence of the Supplement Facts label and/or nutrition support/health claim on a

product. Results of a survey by FDA on supplement users found 58 percent of vitamin and mineral users reported reading the supplement label "always", "almost always" or "most of the time;" of these, 33 percent looked on the label for the benefits of using the product and 22 percent looked for scientific information to support the purported claim (1).

- Attention: the individual sorts out and selectively keeps the information/stimuli that best meets his/her needs or interests, e.g., from information on the package, the person is drawn to the statement "product is 100% natural;"
- Perception: what portion of the information the person receives; and
- Motivation: the general level of interest or desire.

The degree and amount of information searched will depend on the characteristics of the decision (difficult or simple in task complexity), characteristics of the decision-maker (knowledge, abilities, and personality), and information format among other things (86).

Information processing capacity deals with limitations in the amount of information that can be acquired, used, and placed in memory (85). Important components include:

- Comprehension (87): this occurs when the person is able to understand and assign "meaning" to a message or piece of information (important step in process). An important aspect of this is whether the person agrees to accept the information as valid and credible;
- Encoding (87-88): taking several bits of information and "chunking" the information into familiar or easy to identify pieces of information and assigning a new name; and

- Retention/retrieval (87): information is either used immediately or placed in memory to be used for a future decision.

Using our example of the statement "product is 100 % natural" on the supplement label, the individual must then assign "meaning" to the message, particularly if he/she agrees with it and finds it a credible piece of information (whether valid or not). He/she may decide to use it immediately, disregard it (especially if it is unfamiliar or unknown), or place it in memory for future use.

Decision rules include the strategies used to help consumers make decisions and include simplifying strategies called "heuristics" (choice strategies) or "rules of thumb" developed by consumers to limit processing (86,89). This component also relates to information integration in which information retrieved from memory and information from a person's external environment is combined or integrated, together impacting product selection (87,89).

Heuristics can include pre-determined criteria in that the person has an established strategy in mind when selecting an item or the strategy may have to be constructed at the time of the decision (86,89). Individuals who have poor prior knowledge or experience with a product are more likely to develop a strategy for that type of situation (89). Heuristics may be related to product quality, price, nutrition/health information (general or specific), family/personal need, brand name, package features, and ingredients when examining food products. For example, an individual who is scanning the label of a cereal box, may have a pre-determined set of criteria including calories, sugars, and fiber. Brand name and price are two of the most heavily used pieces of information from a

package; and when brand name is evident, less information is sought believed to be due to a "quality surrogate" effect (86).

There are several types of known heuristics (86,89). The type and frequency of their use will vary from situation to situation; in addition, some cases may involve a combination of heuristics. One of the oldest known and frequently used heuristics, is the Satisficing (SAT) heuristic (86,89). With this type alternatives are considered one at a time, in the order they occur in a set of choices. The individual looks at all information on one alternative deemed important; if the item satisfies the pre-determined criteria set, then it is chosen. If not, the consumer continues to evaluate each alternative, and eventually selects the product that best meets the criteria. Another is the Lexicographic (LEX); in this strategy the person determines the most important attribute, and then examines the values of all alternatives on that attribute (86,89). The alternative with the best value on the most important attribute is selected. If two products are tied, then the next most important criterion is considered. An example of this is selecting the less expensive product. A third heuristic relates to the frequency of good and bad features (FRQ) on alternatives (86,89). The consumer may choose an alternative simply based upon the number of good and bad features. For this strategy, individuals would have developed cutoff values for the specific good and bad features. Other heuristics include Elimination-by-Aspects, Equal Weight, Weighted Additive, and the Majority of Confirming Dimensions (pair wise processing of alternatives) (86,89). General properties of heuristics include: comparable (similar attributes/alternatives) vs non-comparable, alternative based (looks at all attributes of single alternative before

evaluating second item) vs attribute based (looks across and within attributes of several products), consistent (same information from one alternative to another) vs selective processing (partial processing), and compensatory (good values on a less important attribute can compensate for poor values on a very important attribute) vs non-compensatory (89).

Basic decision making or problem-solving strategies have been described as (86):

1. Mechanical: individual uses a "trial and error" approach to randomly give several brands a try until finding a satisfactory one.
2. Understanding: individual considers general properties of a product that will meet his/her basic needs; often the first choice has to be acceptable.
3. Insight: decision may occur after a considerable unproductive thought process, i.e., something clicks.
4. Intuition: decision is considered illogical-individual may purchase product based on feelings and hunches, particularly when there is no logical information available.
5. Information processing: individual acquires and processes product and brand information prior to making a decision; usually the most complex type.

Thus, decision-making does not always include a carefully thought out process. Individuals may instead elect to make decisions on a whim, i.e., random selection, habitual or routine purchases, and impulse buying (86).

Some of the more commonly identified factors associated with decision-making include (89): task analysis (ease/difficulty of decision), number of attributes and/or

alternatives (generally, an increase in number leads to a more complex decision), memory capacity (typically only able to handle 7 +/- 2 items at one time (88)), self knowledge and skills, the quality of the information, and source of information (internal/external). Individuals with a low socioeconomic status have been shown to use less information and use more of an alternative based processing versus attribute based (89-90). In addition, Brucks (91) found consumers with more experience and knowledge appeared to search products more selectively and with more efficiency compared to novices. Research has also shown (91) that the accuracy of decisions will decrease with increasing numbers of alternatives; however, when attributes are increased in number, the accuracy level of the decision also increases.

Consumption and learning (85) is the fourth key component of CIP and deals with internal feedback based on the outcomes associated with selections and use of the information in future decisions. *Information environment* makes up the final component discussed. Included is the amount of information, location, format, readability, source of information, self-experimentation, and the ability to process relevant information. Much of the information is derived from external sources, i.e., media, friends/family, product labels. These will also have an impact on the attention, perception, and comprehension stages. Problems with terms and concepts found on labels, lack of knowledge pertaining to unit measures (milligrams, micrograms, grams) and math applications (percent DV), as well as poor understanding of technical terms and/or ingredient names and missing values can all significantly affect the level of difficulty associated with a decision. Increases in the amount of information available to consumers and the source of information may also

contribute to decision problems. Individuals often find it difficult to sort out what may be accurate and beneficial information from that which is considered "hype." Conflicting and misleading information leads to personal conflict, confusion, and poor decisions.

There is no shortage of information available to dietary supplement users. Magazine articles, books, personal experience, word of mouth (friends and family), the dietary supplement label, and health food store personnel are listed as some of the primary sources of information for dietary supplement users (24,27,29,92). Personnel in health food stores who lack formal training in nutrition and herbals are providing what may be dangerous advice to impressionable consumers. It has been shown supplement users do feel the impact of the media and have expressed a desire for more reliable and trustworthy information as well as guidance in supplement selection (49). Yet despite this desire, the majority of supplement users do not seek out the advice of their physician (49). Some reported concerns include the belief physicians are more close-minded when it comes to dietary supplements and often not willing to discuss their use with patients. It is also believed physicians may have a poor knowledge of nutrition and in particular herbal medicine; they may not be current with recommendations for use (49). A survey of 165 medical students and staff at the State University of New York, Health Science Center at Brooklyn (93) produced dismal results when testing for knowledge of ten of the most commonly used herbs in the United States. The highest score was 6 (out of a possible 10); the average score correct was only 1.32 (SD 1.39). In a separate study looking at pharmacists' knowledge and attitudes toward the use of herbal medicine, the average score on the herbal knowledge test was a 6.3 ± 3.3 (maximum 15 points) (94).

Pharmacists appeared to do better with questions related to the use of herbals versus questions targeting specific drug interactions and known adverse effects.

The search for dietary supplements represents a complex decision process. Consumers are exposed to several pieces of information/attributes (such as the nutrition label, front panel claims, terms, unit measures for dose amounts, price, brand, etc.) much of which may be unfamiliar or not well understood. On top of this the vast number of products and brands only serves to confound the task complexity. Whether a consumer actually perceives and comprehends the information leading to retention and retrieval during the decision making process is relatively unknown when looking at dietary supplements. Little is also known about the decision-making strategies and criteria used to make dietary supplement selections. Following are results of studies that have looked at the decision-making process utilized for foods and over-the-counter-medications (OTC).

Studies Related to the Decision-Making Process for Foods and OTC Medications

The first study looked at the effects of the nutrition label on food choice (95). The investigators wanted to know if nutrition labeling had an effect on real purchase behavior. A data set was used containing a list of 1,090 individuals who had a total of 7,606 purchases for children's breakfast cereal. Purchases were made between 22 December 1996 and 4 December 1997. Results showed nutrition attributes were an important factor in choice of products. Taste and the vitamin/mineral content of the cereal had the most significant impact on purchase probability of the brand.

A separate study by McCullum and Achterberg focused on a population of high school adolescents (96). The purpose of the study was to explore the food shopping and label use behaviors among this population specifically related to gender differences. The sample consisted of 41 males and 49 females stratified as shoppers (n=44) versus non-shoppers (n=46). While in the supermarket, participants were provided a list of twenty foods consisting of familiar and non-familiar items. Response categories for criteria used were pre-determined using results of surveys from leading marketers who have looked at adolescent shopping behavior (price, taste, brand, habit, convenience, other, never bought). Participants were asked to verbalize their responses while shopping. The results indicated this group of adolescents found personal preference/taste, custom/habit, cost/price, brand name and front label/health claim as the most important criteria given for food selection. The nutrition label was ranked twelfth. Other reasons given: product was the first they saw, it was a new item, the shape, and the package was conducive for recycling. The most frequently used front label claims were those pertaining to total fat and calories; claims found on the front of the package were used five times more often than nutrient labels. Of additional interest is the fact that those who relied more on claims exhibited a higher interest in nutrition, the majority of which were females. It may be they did not understand the information on the food label, or were more attracted to front label claims. Of the total sample, 17 percent did report having a condition that affected their food choices. Overall, the findings conclude that personal preference/taste, custom/habit, and price/cost were the most important factors in food selection. In terms

of gender differences, males appeared to focus more on the appearance of the package and females were more attuned to claims and the nutrition label.

A third study by Miller et al. (97) also focused on a special population, in this case women aged 40 to 60 years old with non-insulin-dependent diabetes mellitus (NIDDM). A total of fifteen women completed a written questionnaire and in-store shopping interview/food selection observation (qualitative approach). The purpose of the study was to identify important nutrition factors that potentially affect the decision-making process for food selection in women with NIDDM. Three salient criteria were quickly identified as significant contributors to the decision-making process. These included price, nutrition, and family. A total of 65 dimensions were used. From the results gathered from the qualitative research, investigators were able to formulate four basic typologies of shopping behavior: (a) overloaded shopper (special dietary needs, children at home), (b) budget shopper (cost is driving factor), (c) nutrition savvy shopper (always reads the food label; not concerned with cost), and (d) out of touch shopper (lack of knowledge concerning nutrition label/information on package). Other findings: fat was identified as the nutrient of greatest concern, shoppers rarely looked at serving size, and most of the women tended to show extreme interest in the front label claims.

The following four studies specifically address the decision-making process and shopping behavior in purchasing OTC medications in an adult population. Gore and Madhavan (98) based the framework of their study on the premise of the high involvement / low involvement model for decision making. In a high involvement decision the individual goes through an extended problem solving process, i.e., he/she

first recognizes the problem (need OTC medication), then searches for information, does a complete analysis of alternatives, and then makes the decision on which product to buy. Low involvement decisions, in contrast, entail an abbreviated process in which alternatives may or may not be evaluated. The researchers hypothesized consumers who purchased OTC medications would demonstrate a pattern more in line with active information seeking behavior. The sample consisted of 3000 randomly selected consumers from six eastern states. Survey questionnaires were mailed to all individuals; of those received 458 were usable (15.2%). Due to the low response rate, data was stratified to reflect two basic groups: a) those that returned the survey within one week (responders) and b) those that returned the survey after one week (non-responders). Findings, after analysis of the data, showed a mean involvement score of 29.4 for all respondents (out of a possible 42) suggesting a moderate high involvement in purchase behavior. Females produced higher mean scores overall indicating they were more involved than men. Those with a higher education level and income displayed lower scores; the researchers believe this may be due to a higher awareness level and confidence in the ability to understand the label. More consults with a physician or pharmacist also led to a higher involvement score. Age was not significantly correlated and neither was place of purchase, frequency of purchase, or frequency of use.

A second study by Sansgiry and Cady (99) also measured consumer involvement and knowledge of alternatives for OTC medications. The design was focused more on age differences; they hypothesized older consumers (60+ years) would display a higher involvement pattern and would seek out more often expert sources of information

compared with a younger group (18-27 years) of consumers. Personal interviews were conducted and data collected following group randomization. The final results led to a support of the hypothesis. The consumers in the older group were much more involved in the purchase decision for nonprescription medications. Primary attributes of importance for this group included ease of opening the bottle, pharmacist counseling, side effect information, the manufacturer of the product, print size, and the greater choice of medications. For the younger group, the focus was placed more on package size, generic availability, the presence of a child resistant package (safety), and strength and price were equally rated. The older group tended to purchase most of their nonprescription medications in a pharmacy whereas the younger group placed more reliance on the grocery store.

The final two studies also focused on age related differences, however, researchers did not look at the involvement level of the decision-making process. Findings from these studies (100,101) also confirmed the previous study in that there were definite differences in the factors or influences on product evaluation and purchase and sources of information. Stephens and Johnson (100) looked at the age-related differences in terms of factors that influenced the purchase of a cold/allergy medication. Thirty college age (mean 23.8 years) and thirty older (mean 76.9 years) adults completed individual sessions. Half of the participants were randomly assigned to a computerized decision making task first and then written questionnaire; for the other 50 percent the process was reversed. Measures included viewing time, number of alternatives, product label information, and sources of information. For the older adults, formal care providers

and the warning label on the package were listed as primary sources of information when deciding which product to purchase. For the younger aged adults, family and friends were rated as important sources of information. Four individuals reported product packaging and presentation influenced their decision; 13 older and 20 younger individuals rated product convenience as one of the most important influences in product selection. The older adults took much longer to view the information and used less information to make their decision. The authors noted limitations that included the use of a self- report questionnaire, which may have led to socially desirable answers; additionally, the tasking was not in a natural setting/purchase situation; and last, only one medication was used for analysis.

For the remaining study (101) age difference was again the focus of the study; however, these investigators also looked at familiarity as a potential influence on OTC selection. It was believed the older adults would process information more slowly and because of their use of OTC medications, they would demonstrate greater familiarity with the nonprescription medications. The type of OTC medication used was manipulated, and a computerized task display of label information was used. Individuals were asked to select one of four randomly assigned OTCs (antacid, cold, pain reducer, laxative); brand names were removed. The sample was made up of 36 of each age group. All received an oral interview and demonstration on the use of the keyboard. Findings showed that while both age groups were likely to purchase three of the four medications (laxatives more familiar to older group), older adults showed more organization in their search behavior and processed the information much slower than the younger group. Older adults did not

consider cost to be an important factor, and were more concerned with the active ingredients of the product and side effects (particularly with pain reliever). The younger group listed side effects and product uses as important criteria in their decisions.

Overall, results of all studies indicate that while there may be some similarities, there are also variations in criteria consumers consider as important in the decision-making process, especially between different age groups and within special populations (NIDDM). It is also important to note that front label claims faired very well in the studies looking at women with NIDDM and high school aged adolescents. These results are similar to Roe et al. (83) in which 59 percent of the participants used dietary supplements. Individuals in all these studies were reported as either having a high level of interest in nutrition; particularly in the management of a disease, or viewing products with a nutrient content or health claim as healthier. This indicates a greater interest in information and products related to nutrition and health. These individuals appear to be motivated by the purported benefits or rather "what the product can do for them."

Health Belief Model

The Health Belief Model (HBM) remains one of the most widely used models providing a theoretical framework for the study of health behavior in people (102). The model has been used across the continuum of health care to help identify, understand, and explain (predict) a wide variety of health related behaviors (102). The scope of use for this model ranges from screening procedures and detection of disease, disease prevention measures, adherence to medication or dietary behaviors, and clinic utilization. A wide variety of preventive health actions have been studied using this model, some of which

include, but are not limited to: AIDS prevention and safe sex (103,104), prevention of skin cancer / use of sun screen (105-108), and self-breast examination / mammography screening, the latter being one of the largest areas of focus (109-117). The HBM has also been used to try and predict the use of mammography and breast self-examination between different ethnic and cultural backgrounds (118-119).

The conception of the HBM is the result of work in the 1950's by a group of social psychologists concerned with the limited success of screening programs provided by the U.S. Public Health Service (102). Low participation numbers in a free tuberculosis screening program prompted a study to assess individual "readiness" in obtaining x-rays as well as personal beliefs of susceptibility of contracting tuberculosis and the benefits of early detection. Of those with both beliefs of susceptibility and benefits, 4 out of 5 individuals had a voluntary x-ray, and of those with neither belief, 4 out of 5 took no action. Results of the study demonstrated that predicted action to screen was strongly associated with both variables of perceived susceptibility and perceived benefits (102).

The Health Belief Model is a value-expectancy theory grounded on the belief individuals will take preventive action to reduce their risk of developing an illness or disease if they perceive themselves to be at risk (susceptible) of developing the illness; if they believe the illness or disease will have potentially serious consequences; if they believe a specific course of action will reduce their threat (i.e., taking dietary supplements) of getting the illness or disease; and if they believe the benefits of taking the action outweigh the barriers or costs (102).

The six key concepts or constructs of the HBM include: 1) perceived susceptibility-a measure of personal vulnerability to developing a health condition, 2) perceived severity-feelings or beliefs associated with the degree of seriousness of the condition, 3) perceived benefits-the efficacy of available actions to reduce the risk or threat of developing the condition as well as perceptions of non-health benefits, 4) perceived barriers-beliefs about costs or negative aspects of taking a course of action, 5) cues to action-internal or external stimulators that trigger action, and 6) self-efficacy-a confidence in one's ability to successfully perform a specific behavior or recommended action to achieve a desired outcome (102). Other modifying variables that may influence an individual's perception of susceptibility, severity, benefits, and barriers include socio-psychological (self-esteem), structural (knowledge, social support), and environmental factors (media, product information) as well as demographic characteristics (age, income, pre-existing health conditions) (102).

Studies looking at preventive health behavior have identified mixed results in terms of the power of the HBM in predicting or explaining health behavior. No studies known to date have looked at the entire HBM in its ability to predict and explain dietary supplement use. Other studies have used a piece of the model in combination with other health belief theories to explore attitudes and intentions of supplement users (92,120).

Studies Relating Health Belief Model to Dietary Supplement Users

The first study by Conner et al. (92) explored the underlying beliefs relating to dietary supplements in users and nonusers using the framework of the Theory of Planned Behavior (TPB) and additional predictors of intention, i.e., self-identity (being a healthy

eater), health value (individuals' value of health), and a construct from the HBM, perceived susceptibility. The latter was added due to criticism of the TPB model not having perceptions of risk. The TPB postulates that behavior is predicted by intentions to perform the behavior and also by perceived control over the behavior. Intentions themselves are affected by attitudes, subjective norms, and perceived control over one's own behavior. It is believed individuals are more likely to perform a behavior if they have a positive attitude towards it, perceive social pressure from others to perform, and the behavior is within their control. This is the first known study to use the TPB to explore determinants of dietary supplement use. A stratified-sample of 400 women were selected from a database of 15,000 based on self-reported dietary habits and use of supplements. Four different dietary categories were produced (meat eating, fish eating, vegetarian, and vegan); fifty dietary supplement users and fifty non-users were placed within one of those groups. Of the 303 questionnaires returned, results indicated significant differences noted on all TPB variables between users and non-users. Supplement users appeared to display a stronger intention to use supplements, possessed more positive attitudes, perceived more normative pressure to use supplements, and reported having greater perceived behavioral control over the use of supplements. There were no significant differences between users and non-users on self-identity and health value. For susceptibility to illness users were more likely to believe that supplements protect against various health conditions ($p<0.001$) with the greatest difference for colds/flu and arthritis/rheumatism. Health disease, anemia, and menstrual problems were also associated. The authors note that results suggested that taking supplements was an

"act of faith" for users; there was a strong belief the supplements would help them to be healthy, would not cause any harm, and provided an opportunity for them to do something positive for their health. Both users and non-users perceived the media to be a powerful influence on the individuals' decision to use supplements. Overall, the findings indicate that intentions to use dietary supplements were a significant predictor of their use. It should be noted that 60 percent of the sample used dietary supplements. In addition, the sample was drawn from a cohort of women most likely to be interested in diet and health (The United Kingdom Women's Cohort Study).

The second study by Williams et al. (120) combined variables of the Internal Locus of Control scales and Health Belief Model. The study was designed to compare beliefs of middle-aged adults (45-60 years) and older adults (60+ years) who use dietary supplements. The study specifically addressed issues related to nutrition and health and the individuals' perceived level of control over respective health conditions. The scales of the Locus of Control (LOC) model include: internal (control is within one's self or the result of an individuals own action), external/powerful (control is in the power of significant others), and external/chance (where goal attainment is the result of chance, fate, or luck). LOC scales have been shown to be useful in predicting and understanding nutrition behavior. Questionnaires were mailed to 500 individuals in each of seven western states in the spring of 1986. The questionnaire queried for information on use of vitamins and minerals and included variables that addressed health beliefs/attitudes/intentions, perceived health status, and the benefits associated with supplement use. Other items included perceived barriers to health and perceived control

over health matters. The questionnaire was pilot tested with 20 people from each state prior to mailing. The mailing was intended to reach 50 percent of the males and 50 percent of females over 18 years of age. The number of respondents was 1,730 or 57.8 percent. Results showed the middle-aged group was more likely to obtain or acquire information about health and diet from a variety of sources, including health professionals, other than physicians, books, television, magazine, newspapers, and radio compared with the older group. No differences were observed with respect to the use of a health food store as a source of information. With regards to information about vitamins and minerals, the results were relatively the same. Older adults tended to turn to physicians as a source of information. For the health belief questions, the analysis revealed no significant differences between the age groups. Mean scores tended to run higher for the middle-aged group when looking at the internal LOC scale compared with older adults. And for both external LOC scales, the older aged group scored higher suggesting this group perceives more control in the hands of others rather than within themselves; middle-aged adults believed they had more control over their own health.

It is believed the expanded HBM (using all constructs) would serve as a useful tool to identify and explain behaviors and beliefs related to supplement use. Several constructs of the model could play a major role in explaining beliefs, attitudes, and intentions associated with dietary supplement use. As an example, a perceived susceptibility to an illness may be a significant motivator for an individual who believes that taking dietary supplements will reduce their risk to developing the illness. For perceived severity, an individual may believe that dietary supplements will reduce the

severity or symptoms associated with a particular disease or illness. And finally, the influence of product claims on supplement labels (namely health and nutrient support claims) along with word of mouth (recommendations from family or friends) could be strong "cues to action" or triggers that prompt the use of dietary supplements.

CHAPTER IV

METHODOLOGY

Hypotheses

Women are using dietary supplements as evidenced by the percent of use, percent of sales, and availability of products. Research tells us the number and types of supplements being used, reasons for use, and basic demographic characteristics of these users. We know most women obtain information about dietary supplement use not from the primary care physician or health care professional, but instead from a variety of external and internal sources (e.g., media, product labels, word of mouth, and health food stores). We also know from research conducted on food products and over the counter medications that individuals, especially those with a strong interest in health and nutrition, are looking at product claims as important criteria for evaluations of products and as an influence in purchase decisions. Minimal research exists on the safety and efficacy of dietary supplements, particularly herbal medicines. Few studies have used a health belief theory to explore the beliefs and attitudes of individuals who use dietary supplements. In addition, there is also little information in the literature discussing the factors that influence a consumer's decision-making process and purchase behavior related to dietary supplements. At this time, we can only postulate what those specific determinants are. And, despite the encouragement by the Commission on Dietary Supplement Labels to research and find out whether consumers want and can use the

information allowed on dietary supplements under DSHEA, there remains a huge void. There is no known research to date that has probed comprehension and knowledge of the supplement fact label to include safety issues and the terms and concepts associated with the label.

The primary objectives of this study were to investigate: 1) consumer knowledge and comprehension of the supplement label, 2) decision making process for dietary supplements, and 3) whether the framework of the HBM can support the use of dietary supplements. The hypotheses include the following:

1. The criteria used in the decision-making process for selecting dietary supplements at point-of-purchase can be identified;
2. Qualitative analysis will identify five different subgroups of participants based on criteria used during the decision-making process;
3. The perceived benefits of taking dietary supplements will be greater than the perceived barriers;
4. Participants will report a high degree of perceived susceptibility for developing a chronic disease;
5. Participants will perceive that the consequences of having a chronic disease will be severe;
6. Knowledge of the dietary supplement label information will be poor.

Study Population

Women of childbearing age (25 to 45 years) were the focus of this research. Subjects were recruited from the Piedmont Triad region of North Carolina. The sample

size was kept small due to the labor-intensive nature of qualitative research and the abundance of data collected for each participant. Recruitment strategies included placing advertisements in weekly community newspapers (Piedmont Parent, Today's American Woman, Triad Style), the University of North Carolina-Greensboro (UNCG) newspaper (Carolinian), and the city newspaper (News & Record). In addition, flyers were posted in a number of community facilities and businesses believed to be frequented by this age group, e.g., YMCA, YWCA, hair salons, fitness centers, and women's health clinics (See Appendix for sample ads and flyer). The Institutional Review Board at the University of North Carolina at Greensboro reviewed the study protocol and approved the study for human subjects.

The study design was based on quantitative and qualitative research methods. Data collection for this study included three main components: 1) a telephone screening interview to establish participant eligibility, 2) a self-administered written questionnaire, and 3) participation in a point of purchase shopping interview.

Telephone Screening Interview

Women who responded with interest in the study were asked if they would be willing to complete a brief screening interview by telephone to establish eligibility for the study (see Appendix). A general description of the research protocol was provided to the women to include the purpose of the study, required participant activities, as well as assurance of confidentiality. The study was described as a consumer research project being supported by the UNCG School of Human Environmental Sciences. The word

"nutrition" was deliberately avoided to reduce the possibility of participant responses reflecting social desirability efforts of following a "healthy" lifestyle.

Inclusion criteria for the study included: a) age (25-45 years) and b) current consumption of at least one dietary supplement four times weekly. Women who were pregnant or lactating or trying to become pregnant were ineligible to participate and were thanked for their inquiry. It was felt these women would be receiving a dietary supplement as part of their routine medical care. Additional information collected during the telephone screening interview included self-reported height, weight, medical history, and mailing address.

Women determined eligible to participate were asked if they would still like to volunteer for the study. If they agreed to do so, an identification number was assigned to the individual for confidentiality purposes. An appointment was scheduled for the shopping interview and the individual was told she would be receiving a packet of materials in the mail in the next 2 to 3 days. The packet contained a cover letter, a letter containing the location and appointment time of the shopping interview, a written consent form, and a ten-page written questionnaire. Individuals were instructed to fill out the consent form and questionnaire at their convenience and return both at the scheduled shopping interview. Written informed consent was obtained for all women (see Appendix).

Self-Administered Questionnaire

The self-administered questionnaire was designed to collect specific information on sociodemographic characteristics, general nutrition knowledge, self-rated health

status, dietary supplement use, sources for dietary supplement information, and assessment of individual beliefs using Health Belief Model constructs (see Appendix).

Health Belief Model Constructs

Twenty-eight items were formulated using the framework of the Health Belief Model to measure individual beliefs related to general health and dietary supplement use. The questions were designed to include closed-ended responses based on a 5-point Likert scale ranging from 1 (not at all) to 5 (extremely).

The first two constructs centered on general health concerns. Respondents were asked specifically, "How concerned are you about your health?" and "How concerned are you about the possibility of getting sick?" A higher mean score of the two questions combined indicated a greater concern for one's health. Perceived susceptibility to illness or the perceived risk of developing a specific disease was measured by six questions, "Taking all possible factors into consideration, do you think you have much of a chance of getting (heart disease, high blood pressure, breast cancer, diabetes mellitus, osteoporosis, anemia)?" The higher the mean score of the six questions, the stronger the perceived health risk. To explore individual beliefs surrounding perceived severity or seriousness of disease, subjects were first asked five questions, "Suppose you were to get (heart disease, high blood pressure, breast cancer, diabetes mellitus, anemia), how worried would you be about it?" The higher the total mean score for these questions, the greater the woman's perception of how serious the illness would be if she were to develop one of these medical conditions. Six questions then asked respondents to indicate the extent of their confidence in doctors being able to cure disease, specifically

"How confident are you that doctors can cure (heart disease, high blood pressure, breast cancer, diabetes mellitus, osteoporosis, anemia)?" A higher mean score suggested greater individual confidence in the doctor. The average score of these eleven constructs combined were used to measure perceived severity. To measure perceived benefits, individuals were asked "How confident are you that dietary supplements can prevent you from getting (heart disease, high blood pressure, breast cancer, diabetes mellitus, osteoporosis, anemia)?" The higher the mean score, the stronger the perception of the individual's confidence in dietary supplements providing protective health benefits. Three final questions measured perceived barriers related to dietary supplement use. The specific questions included "How much do you feel taking a dietary supplement interferes with your normal activities?" "How much do you feel taking a dietary supplement is costly?" and "How much do you feel taking a dietary supplement takes a lot of effort?" The higher the mean score, the greater the perceived barriers. Heart disease, high blood pressure, breast cancer, diabetes mellitus, osteoporosis, and anemia are all frequent medical diagnoses for women in the United States.

Dietary Supplement Use

For this segment of the questionnaire, current dietary supplement use was assessed for each subject. We were interested in gathering information for supplement type (e.g., calcium, Vitamin A, Ginseng, B complex), dose (milligrams, micrograms, or international units), frequency (number of tablets per day or week) and duration (number of years).

A chart was designed containing a list of twenty-six dietary supplements divided into specific categories: a) multiple vitamins, b) other vitamins, c) minerals, and d) other products. The multiple vitamins were sub-divided into three specific items from which individuals could select from a One A Day, Stress tab, or a Therapeutic Theragram multivitamin. Vitamins A, C, D, and E as well as Folic Acid and B-complex were listed under the "other vitamins." Single supplement minerals included Calcium, Chromium Picolinate, Iron, Magnesium, Selenium and Zinc. The "other products" list consisted of items such as alfalfa, amino acids, protein powder, melatonin, and lecithin; five common herbals were also listed including: St Johns wort, Gingko Biloba, Ginseng, Echinacea, and Valerian Root. Dietary supplements taken on a regular basis, not listed on the chart, were written in as separate items.

To identify dietary supplements taken on a regular basis, individuals were asked to place a check mark in a box that best matched the description of the product they were taking and the frequency of intake. The "number of tablets" or frequency of intake response categories were written in column format: a) none, b) less than once per week, c) 1 to 3 per week, d) 4 to 6 per week, e) 1 per day, and f) 2 or more per day. For coding purposes, an ordinal scale was used with "none" coded as 0, and b – f coded as 1, 2, 3, 4, or 5 respectively. Individuals were also asked to record the number of years of consumption by placing a check mark under the category best describing duration: a) less than one year, b) 1 to 2 years, c) 3 to 5 years, d) 6 to 9 years, and e) 10 or more years. The category "less than one year" was coded as a "1", "1 to 2 years" as a "2" and so on. The numerical codes for both the number of tablets taken and duration of use were put in

a spreadsheet and used for statistical analysis. Space was also provided for individuals to record dose amounts for all dietary supplements with the exception of the multivitamins and B-complex.

Individuals were then queried about attitudes and behavior related to dietary supplement use, specifically: (a) Vitamin C use during a cold, (b) confidence in the adequacy of their diet, (c) initial reasons for taking dietary supplements, (d) source of dietary supplement information, (e) place of purchase, (f) frequency of visits to a health food store, (g) physician awareness of taking supplements, (h) physician recommendation to take a supplement, (i) supplement use by other family members, and (j) the individual's average expense per month for dietary supplements. Numerical codes were assigned to each question to allow for computerized data entry. For questions with a yes or no response only, a value of one was coded for responses marked "yes" and a value of zero for those marked "no." For the questions on self-efficacy, frequency of visits to the health food store, and average monthly expenditures for dietary supplements, the individual was asked to select only "one" response. The responses were coded using an ordinal scale of 1 – 5 or 1 – 4 dependent upon the number of possible responses for each question. The remaining questions for this section were designed to include a "list" of possible choices, any of which the individual could select. If selected, the response was given a value of "1"; if not selected, it was coded as "zero."

Nutrition Knowledge

Ten multiple-choice questions were formatted to assess general nutrition knowledge. Respondents were asked to select one answer from the five answers

provided. The first five questions were designed to assess individual knowledge regarding foods high in vitamin A, vitamin D, vitamin E, vitamin C, and calcium. The remaining questions asked about food fortification, vitamin B6 and oral contraceptive use, folic acid and pregnancy, iron and anemia, and source of an antioxidant. Correct answers were coded as a "1" and incorrect answers as a "0."

Self-Rated Health

Individuals were asked to select one answer from five possible responses (excellent to poor) that best described their current health status. To identify any known medical conditions, individuals were asked to place a check mark under a "yes" or "no" column indicating if they had any of the listed co-morbidities. The list included: heart disease, high blood pressure, breast cancer, other types of cancer, diabetes, osteoporosis, anemia, kidney disease, and chronic pain. Subjects could also write in any "other" known medical conditions in the space provided. Exercise was evaluated by the question, "Do you exercise on a regular basis?" and if yes, "How often do you exercise?" Responses to the latter ranged from less than once per week to more than six times per week. Both the general health question and exercise frequency question were coded using an ordinal scale 1 – 5 or 1 – 4. For current co-morbidities, medical conditions were given a value of "1" if marked as present and a "0" if absent. Questions containing either a "yes" or "no" response were assigned a "1" if the individual selected "yes" and a "0" if "no."

Sociodemographics

Six items were used to assess the sociodemographic characteristics of this study population. Specific characteristics targeted included: age, education level, employment status, race, household size, and household income (for 1999). All responses to the sociodemographic questions were coded using a numerical scale.

Point of Purchase Shopping Interview

The point of purchase shopping interview was an attempt to identify and better understand the decision making process and behaviors related to consumer selection of dietary supplements and individual knowledge of the supplement label. This was accomplished using a methodology combining direct in-store observation of the subject during the actual experience of shopping and use of a "verbal protocol" technique. Verbal protocol asks subjects to verbalize or "think out loud" the thoughts they are processing and analyzing during the shopping experience (121,122). The natural store setting also provided a more realistic shopping experience. The interview protocol was pilot tested with five women representative of the target audience prior to implementing the full study to assess the clarity of the interview questions. No changes were made to the interview guide as a result of this pilot test.

The interviews were conducted in the same, large chain drugstore centrally located within the city to allow for ease of access from all directions. Approval was obtained from the district manager to use the drugstore prior to conducting the interviews. It should be noted this store underwent renovation mid-way through data collection. Although the store changed a couple of brands and no longer carried herbals in a tincture

form (liquid), participants continued to have a full range of products available allowing for a variety of decision tactics that could be employed in the selection process. Interviews were conducted at a time and day convenient for the participant and during open store hours. All interviews were conducted by one of two trained interviewers.

Before beginning the interview, participants were told once again the purpose of the study and provided an explanation of interview procedures. The self-administered questionnaire and written consent form the packet of materials sent to them was collected. The women were asked if they would consent to the interview being audio-recorded and reminded the information would be kept confidential (all 51 women provided consent). Communications involving the point of purchase shopping interview and post-interview questions were audio-recorded for each participant. Every effort was made to make each individual feel at ease. The researcher explained that participants would be asked to shop for a pre-determined list of twelve dietary supplements from the available products on the shelf. The shopping list was designed to include some of the more familiar and frequently used supplements by women (e.g., iron, folic acid, and echinacea) in addition to those that are thought to be less familiar (selenium and chromium picolinate). The list included vitamins, minerals, herbals, and a multivitamin preparation (see Table 4). Prior to actually starting the interview, the women were asked to indicate if they consumed any of these items on at least a monthly basis, defined as a habitual supplement. If not, the item was noted as a non-habitual supplement.

Table 4. Shopping list for dietary supplement selection	
Vitamins/Minerals	Herbal Preparations
Calcium Chromium Picolinate Folic Acid Multivitamin Selenium	Vitamin C Vitamin E	Echinacea Gingko Biloba Ginseng St. John's wort Valerian Root

The women were asked to shop as they normally shop for dietary supplements. The first supplement they were asked to look for was calcium. Each supplement was selected one at a time; no supplements were actually purchased. It was explained to the participants that they would need to "talk out loud" as they shopped. There would be no right or wrong decisions. The interviewer did not answer questions or provide specific information about the dietary supplements that may have biased the selection of any product. However, if the participant appeared puzzled or there was a long period of silence during the interview, the interviewer would prompt the individual by asking open-ended questions. Sample questions included, "Can you tell me what you are looking at while you are deciding which supplement to select?" or "What information is it that is important to you when deciding which supplement to buy?" Questions were also asked to clarify any ambiguous statements or comments. Participants were told any questions they may have about supplements could be addressed at the end of the interview. If a participant stated she would not normally purchase the supplement, she was asked to assume the scenario in which her physician recommended she take the supplement. Once

a product had been selected for the tasked supplement, the participant was asked to clarify and state the main reasons for the selection; or rather, what were the main factors that influenced the decision? This was to help confirm criteria used in the selection of the product.

Following the selection of all twelve supplements, participants were asked if they would be willing to complete a short, open ended interview. In a quiet location of the store, subjects were asked questions to help ascertain individual knowledge of meanings pertaining to supplement safety issues and information and structural claims found on supplement labels (see Table 5). Empty bottles of Echinacea and St. Johns wort were used as visual props.

Table 5. Post-shopping interview questions

1. "What does percent Daily Value mean on the label?"
2. "What does it mean when it says on the label that the percent Daily Value is not established?"
3. What does the following statement mean? "These statements have not been evaluated by the Food & Drug Administration. This drug is not intended to diagnose, treat, cure or prevent any disease."
4. "What is the recommended dose according to the label?"
5. "Who should not take this supplement?"
6. What does the following claim mean? "Echinacea helps support healthy immune function and promotes general well-being especially during the cold and flu season."
7. "What is the active ingredient in St. John's wort?"
8. "What does it mean when a supplement label says that the supplement is natural?"
9. "How do we know that a supplement is pure and does not contain a harmful ingredient?"

All participants received a $20.00 honorarium upon completion of the study. Post interview notes (contact summary notes) were documented by the interviewer immediately upon completion of the interview recording the main factors for supplement selection used by the participant. Audio-tapes were transcribed verbatim for future analysis.

Statistical Analysis

Qualitative Analysis

Twenty transcripts were read to begin the process of identifying the criteria used in participants' decision-making. A preliminary list of key criteria used for dietary supplement selection was established. Standard definitions were developed for all criteria to provide "meaning" to the variable and consistency in coding. New codes identified during subsequent coding procedures were added to the list and definitions established (see Appendix for the list of codes and definitions). A coding sheet for each supplement was created to indicate the criteria used by each participant during the decision-making process (see Appendix). Criteria were coded a "1" if present (e.g., the participant considered "price" in selecting the supplement) and "0" if absent. To determine the inter-rater reliability of the coding procedure, ten transcripts were randomly selected and coded independently by two investigators. The inter-rater agreement of the coding procedure was 85%, considered to be within acceptable limits.

Once the initial coding for all twelve supplements and for every participant was completed, a final tally was performed. The tally included the total number of times each criterion was considered by each participant for all twelve supplements. A data file of the

tally was created using the statistical analysis software, JMP IN (version 4, 2001, SAS Institute Inc., Pacific Grove, CA).

Cluster analysis is a multivariate technique used to group individuals according to similar characteristics so that individuals within the same cluster are more similar to one another (homogeneity) than they are to individuals in the remaining clusters (heterogeneity) (123). For this study, cluster analysis was performed to identify subgroups of participants based on the criteria (or variables) used during the shopping interview for dietary supplement selection. The process of coding transcripts from the shopping interviews led to the identification of 56 different criteria that were being used by participants in decision-making. The list of criteria was too detailed and too large a number for our sample size. To develop a list that would make data analysis more manageable and yet represent the scope of criteria used in the decision-making process, the list was collapsed and reduced to produce a final list of key variables. Items considered less than 20% of the time were deleted, and similar items combined (e.g., dose, % daily value, low/moderate dose, and high dose were all combined under the single variable, "dose"). The ten variables remaining represented those criteria cited as the ones most frequently used by participants during supplement selection. The newly formed cluster variates included: brand, dose, dose frequency, active ingredients, inactive ingredients, price, supplement form, product formulation, supplement quantity, and product information (see Table 6 for definitions).

Table 6. Code definitions for key variables

Active Ingredients: relates to information on the active or main ingredients in the supplement; or the source or form of a nutrient, i.e. calcium citrate or an echinacea extract.

Brand: relates to a preference for a name brand or store brand/generic product.

Dose: relates to the potency of the supplement provided; this also includes preferred dose or inquiries about the general percent daily value provided by a supplement, i.e. total mg/mcg/gm.

Dose Frequency: relates to information given on the package or label describing how the supplement should be consumed; recommended instructions for dose amount and frequency, i.e. serving size, # tablets to take per day.

Inactive Ingredients: indicates the desire for a more "natural" supplement; a preference that the product be free or contains a limited number of additives, i.e. colorings or preservatives.

Price: relates to the total cost of the supplement per bottle or container or per unit (tablet, capsule, soft gel).

Product Formulation: relates to whether a supplement is packaged as either a multi-nutrient/herb blend or single-nutrient/herb formulation.

Product Information: package or label information related to recommended use, specific function(s), or product description; also advertising/front label claims.

Supplement Form: relates to the variety of forms a nutrient/herb is available in, i.e., tablet, capsule, soft gel, lozenge, or liquid.

Supplement Quantity: indicates the total quantity of a product, i.e. the number of pills in the container.

Quantitative Analysis

Cluster analysis was performed using a hierarchical procedure based on Ward's method (an agglomerative algorithm). The procedure groups individuals distinguished by a set of variables based on a measure of similarity between observations (a calculated distance measure-the Euclidean distance). Before performing cluster analysis, however, the researcher needs to pre-select the number of clusters to run in the analysis. Based on information collected during the participant shopping interviews, qualitatively the

researchers believed the analysis would most likely result in a solution with more than three and less than seven clusters. Thus, cluster analyses were performed with varying numbers, ranging from 4 to 6. The distribution of individuals across clusters, and the means and standard deviations for each cluster were evaluated to determine the best solution for classifying the "natural" relationships that existed among participants.

Factor analysis, also a multivariate technique, was conducted on the cluster variates to explore the interrelationships among the set of ten variables and to identify and define the underlying structures within the data set (123). Whereas cluster analysis is concerned with similarities among individuals or objects measured by distance, factor analysis looks primarily at the relationship among variables, or rather how closely related they are to one another. Cluster analyses and factor analyses are both used to simplify qualitative data analyses. The main analysis consists of two parts: 1) identify those respondents who are more closely related to one another in terms of decision-making criteria and percent of frequency of use (cluster analysis), and 2) identify those decision variables that are highly correlated with one another (factor analysis).

A principal component analysis was initially conducted on the unstandardized variables to determine common factor structures (the linear combinations of the variables). Eigenvalues, cumulative variance percentages, and a scree plot were analyzed to help determine the appropriate number of factors to use for further analysis. An orthogonal varimax factor rotation (based on non-correlated variables) was performed on the principal component solution to produce a factor matrix table in which loading factors

for each variable were identified and evaluated. Variables with loading factors of $\geq .90$ were then used to analyze factors by clusters.

A descriptive analysis also was completed to include means and frequency distributions for the Health Belief Model constructs and nutrition knowledge questions from the written questionnaire. A frequency and percentage distribution was completed for the remaining questionnaire variables, to include the sociodemographic characteristics, dietary supplement use, and attitudes and behaviors related to supplement use. One way analysis of variance and x^2 statistics were performed using the total nutrition knowledge score and health belief model subscales (mean scores), to determine if differences existed across clusters. A contrast analysis using Tukey's HSD test of significance was performed on the means of variables found to be statistically significant (level of significance set at $\alpha = .05$). All data analyses were completed using the JMP IN 4.01 software.

CHAPTER V

RESULTS

Recruitment

A total of sixty-one women were recruited for the study. All women were screened by telephone to establish eligibility. Nine women were ineligible to participate due to exclusion criteria (e.g., pregnancy, breast-feeding, over 45 years of age) and one woman withdrew from the study prior to the shopping interview. Thus, the final sample size included 51 women. Primary means for recruitment for this convenience sample were newspaper ads and flyers.

Sample Characteristics

The sociodemographic characteristics of the participants are listed in Table 7. Of the 51 women, the majority were caucasian (84.3%). The mean ($\pm$ SD) age of the sample was 36.0 ($\pm$ 6.0) years and the mean ($\pm$ SD) body mass index was 24.4 ($\pm$ 4.7). All women had at least a high school degree, and 54.5% held a bachelors degree or higher. Over sixty-five percent of the sample had an annual income greater than $30,000.

Health related information regarding current health, exercise frequency, and self-reported health is reported in Table 8. Ninety-six percent of the women reported their health as good to excellent. Thirteen women (25.4%) indicated they currently had a medical condition (e.g., heart disease, blood pressure, diabetes mellitus, and chronic pain). Of this same sample, fourteen women reported having "other" medical conditions,

that included fibromyalgia, allergies, crohn's disease, and arthritis. Forty-one women (80%) indicated they exercised on a regular basis.

Table 7: Sociodemographic characteristics of study participants (n=51)

Characteristics	**Mean (SD)**	
Age (years)	36.0	(6.0)
Body Mass Index (kg/m^2)	24.4	(4.7)
	n	%
Education		
H.S. Diploma	2	3.9
Some College	11	21.6
Bachelors Degree	23	45.1
Advanced Degree	15	9.4
Employment Status		
Full Time ($\geq$ 32 hrs)	28	54.9
Part Time ($<$ 32 hrs)	8	15.7
Full Time Student	5	9.8
Full Time Homemaker	9	17.6
Unemployed	1	2.0
Race		
White	43	84.3
African-American	4	7.8
Native American	1	2.0
Hispanic	1	2.0
Other	2	3.9
Household Size		
Lives w/spouse only	14	27.5
Lives w/children only	4	7.8
Lives w/spouse & children	18	35.3
Lives w/someone other than spouse/children	4	7.8
Lives alone	11	21.6
Household Income[a]		
$<$ $10,000	7	14.3
$10,000 - $19,999	3	6.1
$20,000 - $29,999	5	10.2
$30,000 - $39,999	9	18.4
$40,000 - $49,999	5	10.2
$50,000 - $59,999	5	10.2
$60,000 or more	15	30.6

a Two people did not provide data for this item.

Table 8. Health related information

	Responses (n=50) n	%
Self Rated Health		
Excellent	10	20.0
Very Good	23	46.0
Good	15	30.0
Fair	2	4.0
	Responses (n=51)	
Current Medical Conditions		
Heart Disease	1	2.0
High Blood Pressure	2	3.9
Diabetes Mellitus	2	3.9
Current Pain [a]	8	16.0
Other (e.g., fibromyalgia, allergies, arthritis, migraines)	14	27.5
	Responses (n=51)	
Exercise		
Yes	41	80.4
No	10	19.6
	Responses (n=38)	
Exercise Frequency		
6-7 times weekly	7	18.4
3-5 times weekly	23	60.5
1-2 times weekly	8	21.1

a One individual did not provide information for this item.

Dietary Supplement Use

Table 9 lists the distribution of the number (% of sample) and types of dietary supplements reported as used by participants in the study population. Vitamin C was the most frequently consumed supplement (51%), followed by a multivitamin (43%), and calcium (43%). The most commonly used herbals included echinacea (37%), ginseng (22%), St Johns wort (18%), and valerian root (16%). A number of participants also

reported taking a variety of specialty type products, i.e., bee pollen, cascara sagrada, cat's claw, dong quai, and organic frog mix.

Table 9. Dietary supplement use by percent of sample (n=51)

Supplement Name	% of sample	Supplement Name	% of sample
Vitamin C	51	*Folic Acid*	4
One A Day Multivitamin	43	Alfalfa	4
Calcium	43	Mental/Memory Formula	4
Echinacea	37	CoEnzyme Q10	4
Vitamin E	27	Glucosamine/Chrondroitin	4
B-Complex	25	Flaxseed Oil	4
Ginseng	22	Brewers Yeast	4
Protein Powder	20	Cat's Claw	4
Antioxidant Multivitamin	18	Digestive Aid	4
St Johns Wort	18	Dong Quai	2
Garlic	16	Cod Liver Oil	2
Valerian Root	16	SamE	2
Gingko Biloba	14	Cascara Sagrada	2
Lecithin	14	Vitamin B12	2
Amino Acids	12	Bee Pollen	2
Zinc	12	Astragalus	2
Chromium	10	Vitamin B6	2
Melatonin	10	Kava Kava	2
Magnesium	10	Grapeseed Extract	2
Fish Oils	8	Aswith Gymnema	2
Iron	8	*Stress Tab*	2
Evening Primrose Oil	8	Energy Essential Formula	2
Multivitamin/MultiHerb	8	MyoTone Formula	2
T*heragram*	8	ALJ (respiratory) Formula	2
Multi-Mineral Formula	6	Clear Lung Formula	2
Womens Multi Formula	6	Liver Support Formula	2
Vitamin A	6	Kelp	2
Selenium	6	Organic Frog Mix	2
Vitamin D	4	Zinc/Vit C/Echinacea Blend	2
*GNC Ultr*amega	4		

Italicized words denote the dietary supplements queried for use on questionnaire

Table 10 shows the frequency of consumption for the five most frequently used dietary supplements. Table 11 includes information on the duration of consumption for these same five supplements. It should be noted that 66.7% of the women who reported using echinacea were taking the supplement less than once per week; this may indicate the supplement is not used on a regular basis, but rather as needed, e.g., during colds. Only four women out of 18 reported taking echinacea one or more times daily. Taking into account all dietary supplements reported as consumed, the mean (± SD) number of supplements used per woman was 5.55 ± 3.51, with a range from 1 (9.8%) to 16 (2%) (see Table 12). The number of all dietary supplements reported as consumed by each participant and the percentage across the research sample is provided in Table 13.

Table 10. Frequency of consumption for the five most frequently used dietary supplements

	Response (%)				
Categories	Vitamin C (n=25)	One A Day (n=22)	Calcium (n=22)	Echinacea (n=18)	Vitamin E (n=14)
< once per week	16.00	0.00	4.54	66.67	0.00
1-3 per week	12.00	9.10	9.10	11.11	7.14
4-6 per week	20.00	31.80	13.64	0.00	28.57
1 per day	28.00	45.45	36.37	5.56	28.57
2+ per day	24.00	13.64	36.37	16.67	35.71

Table 11. Duration of consumption for the five most frequently used dietary supplements

	Response (%)				
Categories	Vitamin C (n=21)	One A Day (n=20)	Calcium (n=21)	Echinacea (n=16)	Vitamin E (n=12)
< than 1 year	9.52	10.00	19.05	12.50	16.67
1-2 years	19.05	15.00	42.86	56.25	8.33
3-5 years	19.05	35.00	4.76	25.00	25.00
6-9 years	4.76	15.00	14.29	6.25	25.00
10+ years	47.62	25.00	19.05	0.00	25.00

Table 12. Mean (SD) number of dietary supplements consumed

	Mean (SD)	Range
Main dietary supplements (from chart in questionnaire)	4.74 (3.31)	1 - 15
All dietary supplements	5.55 (3.51)	1 - 16

Table 13. Number of dietary supplements consumed across research sample [a]

No. dietary supplements	n	% of sample
1	5	9.8
2	8	15.7
3	3	5.9
4	6	11.7
5	5	9.8
6	7	13.7
7	4	7.8
8	5	9.8
9	1	2.0
11	3	5.9
12	3	5.9
16	1	2.0

[a] Includes all dietary supplements reported

Sources for information regarding dietary supplements as reported by participants are given in Table 14. The health food store was the primary source of information and used by 72.5% of the participants. Magazines (65.0%), health books (60.8%), friends (47.1%), and family (43.0%) were also cited as common sources. The television (19.6%) ranked higher than the dietitian/nutritionist (15.7%). Additionally, 29.4% of participants listed "other" as a source for information (e.g., the internet and drugstore).

Participants also indicated the most frequently used places for the purchase of dietary supplements were the drugstore/pharmacy (60.8%), health food store (56.9%), grocery store (35.3%), and by mail order (19.6%), in that order (Table 14).

Table 14. Survey measures related to dietary supplement use

Measure/Variable	Yes Responses n	%
Place of purchase (n=51)[a]		
Drugstore or pharmacy	31	60.8
Health food store	29	56.9
Grocery store	18	35.3
Mail order	10	19.6
Direct sales	4	7.8
Other (i.e., Wal-mart, Target)	5	9.8
Information Source (n=51)[a]		
Health food store	37	72.5
Magazine	33	65.0
Health book	31	60.8
Friends	24	47.1
Family	22	43.0
Physician	20	39.0
Co-workers	12	23.5
Television	10	19.6
Dietitian/Nutritionist	8	15.7
Other healthcare professional	7	13.7
Radio	5	9.8
Other (i.e., internet, drugstore, junk mail)	15	29.4
Household member's use of dietary supplements	(n=50)[a]	
Spouse or partner	24	48.0
Children	15	30.0
Self Only	12	24.0
Parent	11	22.0
Other family member	5	10.0
Non-family member	1	2.0
Physician awareness of DS use (n=50)	27	54.0
Recommended use of DS by physician (n=51)	27	52.9
Frequency of visits to health food store (n=51)		
1 or more times per week	10	19.6
1 – 3 times a month	8	15.7
Less than once per month	27	52.9
Never	6	11.8
Average monthly expense for dietary supplements (n=50)		
$0 - $10.00	14	28.0
$11.00 - $20.00	11	22.0
$21.00 - $30.00	9	18.0
$31.00 - $40.00	6	12.0
More than $40.00	10	20.0

[a] A participant could respond to more than one item

Almost half the sample reported their spouse or partner used dietary supplements, and approximately one third indicated their children were also taking them. Over half the sample reported their physician was aware of their supplement use, and again, over fifty percent noted their physician at one time had recommended they take a dietary supplement.

Knowledge

Nutrition Knowledge

Ten multiple-choice questions were used to evaluate the extent of participant's nutrition knowledge. Questions were designed to assess individual knowledge of foods high in certain nutrients, as well as knowledge of specific nutrients that may be used by women under certain conditions (i.e., pre-conception and folate). The distribution in correct responses across all ten questions ranged from 30% to 96%. Two questions posed the most difficulty in terms of incorrect responses: foods high in Vitamin B6 (70% incorrect) and foods high in Vitamin E (66% incorrect). The remaining eight questions had an accuracy rating of 52% or higher, five of which were scored 84% or better. See Appendix for the listing of questions, the correct answer, and the percent of accuracy across the sample. The total nutrition knowledge score (mean $\pm$ SD) was 7.04 ± 1.66 out of a possible 10 points.

Post-Interview Questions

Following the shopping interview, a series of nine questions were asked of all participants related to their knowledge regarding facts useful to consumers when selecting dietary supplements. Three questions (closed-ended) measured the ability to

find specific information directly from the supplement label. The remaining six questions (open-ended) were intended to measure participants' understanding of, or knowledge of, the meaning of terms and phrases related to information found on the supplement label (see Table 15).

With respect to the three closed-ended questions, participants did well with the questions that asked about the recommended dose for either echinacea or St Johns wort and who should not be taking the supplement. The percent of accurate responses was 98 and 77 percent, respectively. For the question related to the active ingredient for St Johns wort, only 26 out of 48 individuals (54%) were able to respond correctly.

The open-ended questions posed more of a problem for many of the participants. Several of the participants were unable to provide an answer for some of the questions, particularly those that related to determining the purity of a supplement and knowing the meaning behind the word "natural" when it was written on the supplement label. There were a variety of different responses given to these questions. For example, when asked how you determine if a supplement is pure, participant comments ranged from, "I really don't know," "trust in the company," "you can't tell that from the label", to trust in the information found on the label, and yet still, the absence of added ingredients. The women were fairly consistent, however, in the responses provided for the questions asking about the immunity claim for echinacea, and the meaning of percent daily value. See Table 15 for a sample of some of the comments received from participants during the post-interview questioning.

Table 15. Results of post-interview questions

Post Interview Questions:

3 Closed-ended questions: (% accuracy)	n	%
1. "What is the active ingredient for St Johns wort?"	48	54%
2. "What is the recommended dose for St Johns wort (or echincacea)?"	43	97%
3. "Who should not take this supplement (St Johns wort or echinacea)?"	48	94%

6 Open-ended questions: (summary of comments)

Focus question	Participant Comments
% Daily Value	That's a good question, but I don't know. That's something I was going to ask you. I take it as meaning there's a certain amount that we need to have of this every day and this tells you how much of it you get. That's the amount that scientists have figured out that we need per day. I'm getting a percentage per day of what my body needs for that particular vitamin.
% Daily Value Not Established	Then it wouldn't make me feel very confident. That means that's its probably not something that's been approved by the FDA as an official nutrient, that's what I understand most of the herbs to be at this point. That the FDA has not approved it or recognizes it as something that would be beneficial to me. ...its not something that has been tested enough to know exactly what the daily value is, its not substantiated in other words.
Immunity Claim	It would say to me, that it is a little bit of insurance for my immune system. To boost your immune system. It helps my immune system to be healthy. I think its an advertising piece; its trying to get me to buy the cure all.
FDA Disclaimer	That means that no regulatory agency has evaluated this, as it says, and therefore there's a lot of freedom in the industry to do whatever the heck you want. Its waiver so they don't get sued for anything. The government is not taking a stance in this. I kind of feel like is a warning that you're on your own if you decide to take it. I would interpret that as take it as a grain of salt...right now there's not a sufficiently high enough level, scientific proof that this is a needed or valued nutritional substance. That means the FDA would rather give me a drug instead of recommending a herb.
Natural	I would hope it would mean that the source was from a plant or animal rather than synthetically produced in a lab. I don't think it means anything now a days. I think people put natural on everything. I take it that sometimes its sort of their way of drawing people; a marketing thing. I would think it means all the ingredients in it occur in nature as opposed to being manufactured by man-made chemicals. I don't know. Do they all say natural? (she's not sure if it's a gimmick or true)
Pure	Good question, probably the trust in the label. We really don't know; we just have to take kind of take somebody's word on it. We don't...there is no way to know because they're not regulated. By reading all the ingredients...you just need to read it all and that's how you know.

Health Belief Model Constructs

Means and standard deviations for each of the five Health Belief Model constructs were used to evaluate participants' general belief patterns related to their use of dietary supplements (see Table 16). Results of data indicate participants did not view themselves as susceptible to the listed medical conditions, were relatively neutral with respect to perceived benefits, and overall, did not perceive that taking dietary supplements was a hindrance in terms of cost, effort, and interference with normal activities. On the other hand, the mean ($\pm$ SD) score associated with perceived health was much higher than average (3.91 $\pm$ .77), indicating participants were generally concerned about their health and the possibility of getting sick. In addition, participants demonstrated a somewhat greater perceived sense of severity with a mean ($\pm$ SD) score of 3.21 ($\pm$ .67) just slightly higher than average.

With respect to self-efficacy, individuals were asked to indicate their level of confidence in response to the question, "how confident are you that you can receive an adequate amount of the vitamins and minerals your body needs from only the foods you eat?" The majority of the sample (88.3%) fell within the range of "not at all confident" to "only somewhat confident" (see Table 16). For the cues to action question, the desire to prevent illness (60.8%) was the most frequently reported response by participants as a reason for starting to take dietary supplements. A feeling of a lack of energy, a recommendation by family and friends, and "other" (e.g., physician recommendation and a concern about the adequacy of their diet) were also common responses among participants (see Table 16).

Table 16: Description of subscales - Health Belief Model (HBM)

HBM Statements	No. Subscale Items	n	Mean Score (SD)[a]
1. Perceived Health	2	49	3.91 (.77)
How concerned are you about your health?			
How concerned are you about the possibility of getting sick?			
2. Perceived Susceptibility	6	48	2.24 (.69)
Taking all possible factors into consideration, do you think you have much of a chance of getting _____ (heart disease high blood pressure, breast cancer, diabetes mellitus, osteoporosis, and anemia, respectively)			
3. Perceived Severity	11	46	3.21 (.67)
Suppose you were to get _____ (heart disease, high blood pressure, breast cancer, diabetes mellitus, and anemia, respectively, how worried would you be about it?			
How confident are you that doctors can cure _____ (heart disease, high blood pressure, breast cancer, diabetes mellitus, osteoporosis, and anemia)?			
4. Perceived Benefits	6	49	2.91 (1.01)
How confident are you that dietary supplements can prevent you from getting _____ (heart disease, high blood pressure, breast cancer, diabetes mellitus, osteoporosis, and anemia)?			
5. Perceived Barriers	3	51	2.13 (.64)
How much do you feel taking a dietary supplement interferes with your normal activities?			
How much do you feel taking a dietary supplement is costly?			
How much do you feel taking a dietary supplement takes a lot of effort?			

6. Self Efficacy

How confident are you that you can receive an adequate amount of the vitamins and minerals your body needs from only the foods you eat?

Categories (n=51)	Response (%)
a. Not at all confident	31.4
b. Slightly confident	27.5
c. Somewhat confident	29.4
d. Very confident	11.8

7. Cues To Action

What caused you to start taking dietary supplements?

Categories (n=51)	"Yes" Response (%)
a. Illness	27.5
b. Desire to prevent illness	60.8
c. Feeling a lack of energy	54.9
d. Recommendation by a family member or friend	31.4
e. Dietary supplement advertisement	13.7
f. Other (e.g., MD recommendation, concern with adequacy of diet)	49.0

[a] For HBM statements 1 – 5, a 5-point Likert scale was used: 1 (not at all) to 5 (extremely)

Factor Analysis

A principal component analysis was performed (using the final data matrix) to help identify the number of factors in the decision-making process for dietary supplement selection. A 2-factor structure was determined to be the best solution, accounting for 59.7 % of the total cumulative variance. Price, supplement quantity, and dose loaded on factor 1; this factor was labeled "primary criteria" (Table 17). Individuals, who consider price, most likely also consider dose, and supplement quantity in the decision-making process. Inactive ingredients, active ingredients, dose frequency, product information, dose, product formulation, and supplement form comprised factor 2, named "secondary criteria." The variable "brand" did not load on either factor (inverse relationship) and was deleted before running the cluster by factor analysis, and the variable "dose" loaded high on both factors. Thus, when a participant considers or uses brand, she is less likely to consider criteria from either factor 1 or factor 2.

Table 17. Factor structure for the 10 most commonly used variables in decision-making

	Factor 1 Loadings	*Factor 2 Loadings*
Factor 1: Primary criteria used in decision-making		
Price	3.37	-0.08
Supplement Quantity	3.03	0.22
Dose	2.19	1.41
Factor 2: Secondary criteria used in decision-making		
Inactive Ingredients	0.40	2.59
Active Ingredients	0.52	2.33
Dose Frequency	0.84	2.24
Product Information	0.18	2.17
Dose	2.19	1.41
Product Formulation	0.05	1.29
Supplement Form	0.59	0.93
Variable not loading on either factor:		
Brand	-1.79	-0.77
Eigen value	36.12	18.23
% Variance explained	43.53	21.97

The value used to determine if variables were loading on factors was > .90.

Cluster Descriptions

Based on the identification of key variables and percent of use during decision-making, cluster analysis identified five distinct groups of women. The five-cluster solution was deemed a better solution with the best distribution of individuals across clusters and the least variability among variables. Labels were then assigned to each cluster as a means of characterizing the group according to the strategies used for dietary supplement selection. The means and standard deviations for each cluster are reported in Table 18.

Table 18. Mean (SD) for each key variable by cluster

Variable:	Cluster 1 (n=9)	Cluster 2 (n=8)	Cluster 3 (n=9)	Cluster 4 (n=16)	Cluster 5 (n=9)
Active Ingredients	1.33 (1.22)	2.25 (1.49)	7.78 (2.05)	4.06 (2.31)	2.89 (0.93)
Brand	2.78 (2.33)	7.00 (3.62)	4.11 (4.26)	2.31 (1.78)	8.22 (1.64)
Dose	7.56 (1.94)	3.75 (2.05)	11.11 (0.93)	10.81 (1.28)	9.11 (2.09)
Dose Frequency	1.89 (1.62)	0.75 (1.03)	7.00 (2.50)	5.06 (2.79)	2.33 (1.50)
Inactive Ingredients	2.33 (2.29)	1.25 (2.82)	9.00 (2.45)	1.75 (1.95)	1.33 (1.32)
Price	7.56 (2.07)	2.25 (1.83)	8.89 (3.92)	10.31 (1.35)	9.56 (2.65)
Product Formulation	2.56 (1.24)	5.50 (4.31)	6.11 (2.52)	5.38 (2.16)	4.00 (1.66)
Product Information	1.33 (1.50)	3.12 (3.31)	6.89 (2.93)	4.62 (2.53)	4.00 (2.06)
Supplement Form	3.22 (2.49)	1.00 (1.41)	4.11 (1.36)	2.69 (1.89)	1.78 (1.72)
Supplement Quantity	5.67 (1.87)	1.38 (1.30)	7.56 (3.21)	7.31 (3.48)	7.44 (2.30)

The primary criteria, price, dose, and supplement quantity were being used by participants in four out of five clusters during decision-making. Participants in clusters 1, 3, 4, and 5 were strongly influenced by these criteria and considered them in selecting dietary supplements, some to a greater degree than others. What distinguished these clusters from one another, was the influence of the secondary criteria (e.g., product information, active ingredients, inactive ingredients, and dose frequency). Cluster 2 was unique from the remaining clusters. This group of women were the least concerned with price, dose, and supplement quantity and only moderately influenced by secondary

criteria (primarily product formulation). The variable "brand" was the strongest indicator for cluster 2.

A final analysis was done to compare the mean (± SD) factor scores by each cluster (see Table 19). Results for cluster 2 indicate a strong inverse relationship to both factor 1 and 2. Clusters 1, 2, 4 and 5 demonstrate an average to positive relationship to factor 1. Cluster 3 has the highest mean score for factor 2, indicating a strong positive relationship. And clusters 1, 2, and 5 show a strong negative relationship to factor 2. A description of each cluster follows.

Table 19. Mean (SD) factor score by cluster

Cluster	n	Factor 1 Mean (SD)	Factor 2 Mean (SD)
1	9	-0.08 (0.41)	-0.78 (0.43)
2	8	-1.72 (0.42)	-0.43 (0.76)
3	9	0.17 (0.92)	1.63 (0.53)
4	16	0.57 (0.62)	0.03 (0.74)
5	9	0.42 (0.71)	-0.53 (0.29)

Bargain Shoppers

Nine out of 51 participants were included in the first cluster "bargain shopper." Major decision criteria for this group of women were dose amount, cost of the product, and the volume or quantity of the supplement provided in the container. For the most part, these women spent little time comparing products and were quick to make their

decisions with regards to supplement selection. In fact, one participant compared herself to a male shopper and said, "I go in, get it, and get out."

The potency or dose amount was one of the first things this group looked at followed by price and quantity. For some of these women, it was the desire for a higher dose, and in other cases, when the individual was unfamiliar with the nutrient or herb, a lower dose was preferred. Once the dose and quantity were determined, price was then examined. The women were definitely price conscious. One woman stated, "even if I was a millionaire, I'd probably still look at cost; its just a habit." More often than not, however, they wanted the best value for their money or the better bargain. Several of the women made decisions based on the value-added benefit of the product, i.e. a higher dose or a greater number of pills or tablets for the least amount of money. One woman commented, after making her selection for selenium, "it seems like you get more bang for your buck." The women were also attracted to sales advertisements, or signs indicating a rebate, or buy one, get one free offer. As an example, one participant selected a gingko biloba product based on the premise of the advertised "buy one get one free" offer; she commented this was a "real bargain."

The product being a brand name or generic/store brand was not a major contributing factor, however, was considered to a lesser degree by some women in the decision process. For example, a lot of the decisions for the multivitamin were based on brand recognition or familiarity (i.e., Centrum and One A Day brands). For the remaining supplements, however, even if brand was a factor, price still contributed significantly to the final selection.

Brand Shoppers

Eight women out of the sample clustered into what was labeled the "brand shopper." This cluster was most influenced by the groups' preference for a brand name product. The women in this cluster were also moderately influenced by the variables, product formulation and product information. The participants did not spend an extensive amount of time comparing items and reviewed little information other than front label claims and manufacturer descriptions for usage of the nutrient/herb. Price, dose, supplement quantity, dose frequency, supplement form, and active/inactive ingredients were the least important criteria considered by this group.

For this group of participants, their preference for a brand name product was associated with three main factors: perceived quality, family influence/familiarity, and package color/product information. In many cases it was a combination of two or more of these that led to a particular brand being selected. With respect to product quality, one participant stated, "I pretty much stay away from generics actually; I don't know why other than I just sort of, I personally feel like they're just not as good." The perception was that the generic/store brand was not as good a quality as the brand name. Another participant commented, "I would get it as opposed to the Kerr drug brand, just because as a general rule, some things you can get as a store brand, and some things you can't; in vitamins, I wouldn't, in supplements I wouldn't, not necessarily."

Family influence/familiarity was probably the strongest influence. Several of the participants selected brand names they were familiar with, or products they had used in the past or were currently using. For three of the participants, the decision to choose a

brand name was one of trust. The participants chose the brand names their mother or sister used, or products purchased while they were growing up. One woman stated, "I think I would buy Nature Made, and I think I would buy that because my mother used to take these, and I trust what she does." Another participant commented, "I would probably take the Natures Resource in the St. Johns wort, just because my mother and sister both take that, and they're totally happy with it; and I trust them." For one participant, it was a matter of recognition. She preferred the Nature Made brand, because it was one that she recognized as being sold and recommended at one of the health food stores she visited.

Package color and product information, in the form of the manufacturer description were also strong persuaders. One individual based her decision to go with a particular brand name because of the color of the bottle; she claimed it looked "more nature like." The manufacturer description on product use and function was also influential. Those brands that had clear, concise, and easy to understand narratives were preferred over others. In terms of product formulation, participants considered this only when a complex or multi-supplement blend was favored (within a particular brand name).

Information Gatherer Shoppers

Nine women formed the third cluster, which was best described as "information gatherers." Many of the participants in this cluster were unfamiliar with supplement terms found on the label such as USP, PEG, standardized, IU, mcg, and water-soluble. One participant noticed vitamin E was available as a water-soluble, and commented that she knew vitamin E was a fat-soluble vitamin, so was curious as to why the product said

"water soluble" on the label. She attributed this to an advertising gimmick. Several women also noted they did not know or were unable to recognize many of the inactive ingredients listed on the label. As one participant said, "I don't know why I read these ingredients, because I don't know what half of them are." The names of several additives also invoked suspicion. One of the participants, after reading the list of inactive ingredients stated, "this stearic acid just sounds kind of bad, and silicon dioxide doesn't sound very good, and of course, carbonate sodium doesn't sound very good either." Questions were raised among the group with regards to the form of Vitamin E and ginseng to use, and confusion was apparent with respect to the "correct" dose to take for some of the supplements.

Cluster 3 was primarily characterized by several of the key criteria: product information, dose, price, supplement quantity, active ingredients, inactive ingredients, package formulation, and dose frequency. The variables brand and supplement form were also considered, but to a lesser degree. Participants spent considerable time looking at several different attributes for a variety of brands and products. Their search patterns during the decision-making process was not always consistent, and the final selection was not always based on the same criteria, but rather a combination of criteria.

These participants, during the decision-making process, were essentially using eight out of ten key variables. Of highest consideration, however, was a shared interest in the number and type of additives in a product. Participants in this cluster placed an emphasis on avoiding or narrowing the number of inactive ingredients. As one participant said, "sometimes there's a lot of extra things that are in it that don't have to be

in it...for instance, colors and things like that, and wax...I just would have a tendency to look at more that has less in it." Another commented, "I usually look for the stuff with the least amount of extra ingredients in it." Three of the women literally counted the number of the inactive ingredients listed on the label, and of the products in hand, went with the least number of additives.

Some of the participants who preferred a brand name versus a store brand would look for those brands that had the shorter list of inactive ingredients. A product with a short list of additives was also perceived as being more pure or natural. For instance, one participant commented, "this one has got tons of ingredients that I've never seen before; I'd probably go with this [other] one because it just seems more pure." And another woman stated, "I try and buy things without preservatives...not that I know like every preservative, but I try and be like as natural as I can." If cost was a factor, more often than not, finding a product with the least amount of additives was still a major consideration.

Many of the women in this cluster were also concerned about the absorption of the product. They looked at dose frequency as it related to absorption. They were also attracted to advertising claims such as "100 percent highly absorbable" and thought brand names containing the words "nature" or "natural" conveyed to them the product would be better for the body, or better absorbed.

Convenience Shoppers

Cluster 4, the largest of all the groups, was comprised of 16 participants and labeled "convenience shoppers." This cluster was largely influenced by the variables

dose, price, supplement quantity, dose frequency, and product formulation and to a smaller extent by supplement form, product information, active ingredients, and brand. Inactive ingredients had the weakest influence on this group. Of all the criteria, dose, dose frequency, supplement form, supplement quantity, and price were principal factors for these women in deciding what product they would buy.

The women in this cluster were most concerned with the usefulness or convenience of the product from a variety of standpoints. For this group, dose and dose frequency went hand in hand. The potency (dose) of an item and the dose frequency were important criterion in almost every decision made by this group. Several participants were drawn to items with a lower potency; they wanted the convenience of being able to adjust how often they would take the supplement. A lower dose gave them greater flexibility with respect to how many of the pills they would take per day. A lower potency was also favored when a participant was unfamiliar with a supplement.

A greater number of women, however, were more focused with getting items with a higher dose. They wanted a product that offered higher potency that enabled them to take fewer pills per day to meet their daily requirements. One participant gave the primary reason for her product selection, "because you get the largest dose, and you only have to take it one time; you don't have to keep taking 3 or 4 pills a day." Another noted, "...this has 350 milligrams and its only one capsule a day as opposed to two or four." For a few of the women, dose frequency was their number one concern. Products that recommended taking the least number of pills were singled out from the others. As an example, one participant stated "...one or two tablets daily only, so I don't have to

remember 3 times a day, 3 tabs at a time. No thank you." Other participants found a complex or multi-supplement blend offered them the convenience of taking fewer pills. One woman remarked, "yeah, the complex formula, because see I'm taking those two already (folic acid and B complex), and the less pills I have to take in the morning to get what I need, the more I like it."

For a few of the participants, purchasing a large quantity of the supplement meant fewer trips to the store. As one participant stated, "...I would go with the larger one, because I take a lot of it; I don't want to have to keep running back to the store." Another woman commented, "...again, the amount I'm getting, if I'm going to take a product, I don't want to turn around and go to the store 3 to 4 times a week."

For some of the participants, supplement form was considered a criterion for convenience. Products that were packaged as a soft gel or capsule were perceived as being easier to swallow. One woman noted, "I would look to see if it's a tablet, because if I can get something in a soft gel or a capsule, it's usually easier to swallow." Two of the participants saw the chewable form of vitamin C as a convenience from the viewpoint of their family also being able to take the supplement. One participant stated, "I like to get the chewable tablet, and the reason I do is because, then my family can also chew the tablets and my kids like it."

Price was considered throughout the decision process, however, for most of the participants, it was utilized more as a tie-breaker between otherwise comparable products. If the more important criteria (dose, dose frequency, and supplement form) were similar, then price was often the deciding factor. The purchase of a discount or

store brand was not a major issue for the majority of these women. However, if price was comparable between a brand name and the store brand, the brand name was usually preferred. The various reasons included familiarity, package color, and the perception of a higher quality product. As one participant put it, "Because their name brand is a little better than Kerr's and the money is the same, so why not." Product information was considered and used when the women were unfamiliar with a supplement. They read the description to learn more about the supplement with respect to suggested uses and the recommended dose.

Quality Shoppers

Nine out of 51 participants were in the fifth group, called "quality shoppers." Cluster 5 was most influenced by dose, price, supplement quantity and brand, and moderately influenced by product information and product formulation. For the most part these women were also concerned with price and looked for products that offered a higher dose and/or greater quantity of pills for the least amount of money. The group's most notable characteristic, and the one that distinguished them from clusters 1, 3, and 4, was their shared preference for a "quality" product.

For several of these participants, purchasing a brand name meant getting a quality product. One of the women compared it to buying a prescription medicine; she would not use a generic product when it came to her health. When dose, price, and quantity were comparable across products, several participants opted to buy the brand name. Though they could not always state a reason, they personally felt the brand name was a better product. For example, one woman stated, "now that I see that it's the same price as

Nature Made, I would probably get Nature Made figuring it might be a little better quality." Another commented, "I would go with Natures Resource, because it's the same price; I just have the concept that that might be a better brand, but I'm not sure if I'm right." For a couple other women, it was more brand recognition or trust. One participant remarked, "I am familiar with the brand, it's a reasonable brand as far as quality and price." And another stated, "I would get the Nature Made, I trust the brand." Package color or appearance was also a dominant factor as to whether a participant would select a brand name. As one participant commented, "I'm very subjective about colors...I mean if we were doing this for Kerr specifically, I'd tell them they need to change their packaging. I mean, now this one is pretty (brand name); I would buy this." Another stated, "ah 400 milligrams, the same thing, they're the same price, this is where you can get into the subjective stuff, like how pretty is the package." She admits, "I am a sucker for packaging...if I'm trying to save money, I go for cheap; if I'm not trying to save money, sometimes, I will buy something based on a package. It just depends." And still another woman remarked, "...here's the generic, the Kerr brand, and I just, I don't know whether it's the look of the bottle or whatever; it just doesn't seem appealing to me...I know its probably the best, I mean its just as good as anyone else."

For one woman, the definition of quality meant that the product had to be made in the United States. She commented that she would look for this criterion first, and then after deciding on a brand, would then compare dose, quantity, and price. She believed the quality standards for products in the United States were at a higher level compared to standards for products made abroad.

Another woman was adamant that the product label contains some sort of evidence for purity and potency testing. She noticed the initials "USP" on a label and commented, "these people would probably be the people that I'd pick because they've done some kind of testing; they guarantee purity and potency and that to me is critical." This same participant and a few other women also looked for the word "standardized" on product labels for herbs. To these women it indicated that the product had undergone some form of testing.

Several of the participants were also concerned with Vitamin E. They only wanted the "natural" form of the vitamin and did not feel the synthetic form was as good as the natural. As one women stated, "my criteria for Vitamin E would be that it is the natural stuff; it's not a mixture of the D and L and the this and that, I just want the pure stuff. I just think that's better." Many of these women, however, could not recall the name for the natural Vitamin E. One participant who was looking at Vitamin E products said, "I would try to find a Vitamin E that was the natural variety, and right now I can't remember, I believe its called tocopherol."

The front label claim or marketing of a product was also an important feature for many of the women in cluster 5. As one participant noted, "marketing or advertising is a big thing to me, especially when I'm not sure about what to buy." Another woman adds, "labeling is everything." Several of the women were drawn to products with claims or multi-supplement blends that they felt would enhance their health or would be able to offer a benefit or support to them. One participant stated, "its always to get the ultimate punch." She looked for things that would benefit her health, and she would pay the extra

money if it were important to her. Another woman seeing a claim for weight loss remarked, "I don't know the brand at all, but the reason I would buy this is awful; because it says it helps metabolize fats." She said she would buy it for the weight loss claim and would probably pay the extra money. And another participant explaining her reason for her selection for a ginseng product, "...I would choose the Natures Resource ginseng siberian, it has the stress support and I definitely need that."

Cluster Comparisons

The sample was very similar with respect to sociodemographic characteristics; as a result, no comparisons could be performed with regards to differences in gender, education, race, and income.

One way analysis of variance tests and contingency tables were used to determine if there were any significant differences between clusters. There was no statistically significant difference between clusters for the dependent variables body mass index, exercise level, visits to health food store, and supplement expense ($p > 0.05$). There was also no difference between clusters with regards to the total nutrition knowledge score ($p > 0.05$) (see Table 20). An analysis of cluster by interview time, however, did show a statistically significant difference between clusters ($p < 0.0001$). Table 21 shows the differences (mean $\pm$ SD) between clusters with respect to interview times (minutes). Contrast analysis, using the Tukey HSD test for significance, indicated clusters 1, 2, 4, and 5 were significantly different from cluster 3. This result is in agreement with the description given for cluster 3. Participants in this cluster spent a considerable amount of

time comparing products and brands across several attributes before making a final decision.

Table 20. Mean (SD) knowledge score by cluster [a]

Cluster	n	Mean (SD)
1	8	7.12 (0.61)
2	6	6.50 (0.70)
3	9	7.22 (0.57)
4	15	7.07 (0.44)
5	8	7.12 (0.61)

[a] 10 Total points were possible

Table 21 . Interview time (minutes) by cluster

Cluster	*Interview time* Mean (SD)
1	40.00 (5.79)[a]
2	42.50 (6.14)[a]
3	78.89 (5.79)[b]
4	49.06 (4.34)[a]
5	42.78 (5.79)[a]

[a] Values with different superscripts are statistically significant from each other ($p < 0.0001$); contrast analysis (Tukey HSD test for significance) showed clusters 1, 2, 4, and 5 were significantly different from cluster 3 ($\alpha = 0.05$).

Contingency analyses using frequency distribution data were run to determine if differences existed among clusters with regards to place of purchase and source of information for dietary supplements. Two responses indicated a statistically significant

difference among clusters. The response "grocery store" resulted in a x^2 value of 9.43, DF 4 ($p = 0.05$).(Pearson ChiSquare). Participants in cluster 1 (67%) were using the grocery store as a place of purchase for dietary supplements compared with 16 to 39 percent of participants in the remaining clusters. Additionally, none of the participants in cluster 2 used the grocery store for purchasing supplements. Recalling information from the cluster descriptions, the women in this group were influenced by the variable brand. The response "television" from the list of sources of information for dietary supplements resulted in a x^2 value of 9.41, DF 4 ($p = 0.05$) (Pearsons ChiSquare). Fifty percent of the participants in cluster 2 indicated they used the television as a source for information compared with 20-25 percent in clusters 1 and 4, and zero percent in clusters 3 and 5 (table not provided).

With respect to the health belief model, perceived barriers (F ratio = 3.13, DF 4, $p = 0.02$) and the cues to action response for "ads" (DF 4, $p < 0.01$) were the only variables that resulted in a statistically significant difference between clusters (see Tables 22 and 23). A contrast analysis using the Tukey HSD method for a test of significance was conducted on the result for perceived barriers. Results revealed clusters 2 and 3 were significantly different from cluster 5 ($\alpha = 0.05$). The x^2 value for "ads" was 13.53 (Pearson ChiSquare); results indicated participants in cluster 2 appear to be paying more attention to advertisements.

Table 22. Analysis of clusters by health belief model subscales (concerns, susceptibility, severity, benefits, and barriers)

	Cluster 1 (n=8)	*Cluster 2* (n=8)[a]	*Cluster 3* (n=9)	*Cluster 4* (n=15)[a]	*Cluster 5* (n=9)
Health Belief Model *Constructs*			*Mean Score (SD)*		
Perceived Concern (n=49)	3.81 (0.28)	4.00 (0.28)	3.89 (0.27)	3.83 (0.21)	4.06 (0.27)
Perceived Susceptibility (n=48)	2.15 (0.25)	2.27 (0.25)	2.39 (0.24)	2.27 (0.19)	2.07 (0.24)
Perceived Severity (n=46)	2.92 (0.24)	3.14 (0.24)	3.17 (0.23)	3.39 (0.20)	3.32 (0.23)
Perceived Benefits (n=49)	2.33 (0.35)	3.35 (0.35)	2.65 (0.33)	3.16 (0.26)	2.89 (0.33)
Perceived Barriers[b] (n=51)	2.11[b] (0.20)	2.50[b] (0.21)	2.48[b] (0.20)	2.02[b] (0.15)	1.67[c] (0.20)

a Numbers are less than the study population because of missing responses

b Statistically significant result ($p = 0.02$) (numbers with differerent superscripts differ from each other); contrast analysis using Tukey's HSD method indicated Clusters 2 and 3 were significantly different from Cluster 5 ($\alpha = 0.05$)

Table 23. Analysis of clusters by health belief model subscales (self-efficacy and cues to action)

A. Self-efficacy Question (confidence in receiving an adequate amount of vitamins and minerals from only the foods eaten)

Categories	Response (%) by cluster (n=51)			
	Not at all Confident	*Slightly Confident*	*Somewhat Confident*	*Very Confident*
C1: Bargain Shopper	12.50	21.43	13.33	33.33
C2: Brand Shopper	18.75	7.14	20.00	16.67
C3: Information Gatherer	6.25	35.71	13.33	16.67
C4: Convenience Shopper	43.75	28.57	26.67	16.67
C5: Quality Shopper	18.75	7.14	26.67	16.67

B. Cues To Action Question (motivations for starting to take dietary supplements)

Categories[a]	"Yes" Response (%) by cluster (n=51)					
	Illness	*Desire to Prevent illness*	*Lack of energy*	*Recd'n by family/friend*	*Supplement ad*	*Other*
C1: Bargain Shopper	14.29	16.13	10.71	12.50	0.00[b]	20.00
C2: Brand Shopper	21.43	19.35	17.86	18.75	57.14[c]	8.00
C3: Information Gatherer	21.43	16.13	14.29	12.50	0.00[b]	16.00
C4: Convenience Shopper	28.57	32.26	39.29	37.50	42.86[b]	32.00
C5: Quality Shopper	14.29	16.13	17.86	18.75	0.00[b]	24.00

[a] Participant could select more than one response

[b] x^2 (4) = 13.53, $p < 0.01$; numbers with different superscripts differ from each other

Analyses were also performed to determine if there was a difference between clusters with respect to the average number of dietary supplements consumed (see Table 24). Results indicated that there was a statistically significant difference when comparing

the average number of main dietary supplements reported against the different clusters ($p < 0.05$). Findings from a contrast analysis (using Student's *t* test) showed cluster 3 was significantly different from clusters 4 and 5. The mean scores for each cluster indicate participants in clusters 4 and 5 are using a greater number of dietary supplements on average compared with clusters 1, 2, and 3.

Table 24. Analysis of cluster by mean number of dietary supplements used

Cluster	Main dietary supplements reported (chart in questionnaire)	All dietary supplements reported
1	4.89[a]	5.33
2	3.50[a]	4.12
3	2.56[a]	3.44
4	5.62[b]	6.50
5	6.33[b]	7.44
p Value	0.05	0.07

[a] Numbers with different superscripts differ from each other ($\alpha = 0.05$)

CHAPTER VI

DISCUSSION

Females between the ages of 25 to 45 years, who used dietary supplements, were the target population for this study. The women in the sample were a very homogenous group, representative of other female supplement users. Similar patterns were observed with respect to levels of education, income, ethnicity, and self-reported health (6-9,11-13,18). The type and average number of dietary supplements consumed by the sample were also consistent with current literature (9,13,20,49). Some of the women reported taking supplements that could be considered as non-mainstream (e.g., astragalus, bee pollen, cats claw, organic frog mix), and poorly researched. The use of these products poses a significant level of concern regarding consumer safety since sufficient scientific clinical data supporting the purported benefits is limited at this time. The participants also obtained most of their information about dietary supplements from sources identified in previous studies, i.e., employees of health food stores, magazines, health books, and friends and family members (9,14,20,23,92).

The primary objectives of this study were based on three things. Our goal was to explore and begin to identify and better understand the decision-making criteria used during dietary supplement selection. This has been an area of research that has not been investigated previously. Second, we believed the expanded Health Belief Model would allow us to explore individuals' health beliefs and behaviors related to dietary supplement

use. And finally, it was important to assess individuals' knowledge and understanding of information found on the dietary supplement label, once again an area of research that has received little attention. Each of the objectives is discussed below.

Decision-Making

The main purpose of the study was to attempt to identify and better understand, in this sample, the decision-making criteria used at point-of-purchase for selecting dietary supplements. Ten key variables were identified as the determinant criteria being used across the sample in making supplement selections.

While the women were very homogenous with respect to demographic characteristics, they were not similar in their decision-making strategies. Results of this study demonstrated that women were using a variety of strategies that varied considerably from person to person, and from supplement to supplement. Similar findings were noted in studies that looked at food selection and the purchase of over-the-counter medications (96-97,99-101). Cluster analysis identified five distinct types of purchase behaviors based on the type and frequency of use of the main criteria. Four out of the five clusters were using what was labeled the "primary" criteria (price, dose, and quantity). These three variables could be referred to as fundamental or value driven criteria, since they are often considered in the purchase of other products. What distinguished these clusters from one another, was the individuals' use of the "secondary" criteria. As an example, participants in cluster 3 (Information Gatherers) considered the primary criteria, but were more strongly influenced by the secondary criteria, namely inactive ingredients. And cluster 2 (Brand Shopper) was significantly different from all

other clusters; this group of women was most influenced by the variable brand, which did not load on either factor.

Williams states in his book (86) on consumer behavior that there are different levels of problem solving. The first is what is considered "extensive." This type of problem solving occurs when there is a high degree of deliberation involved in deciding what product to purchase. Individuals with little or no experience with a particular product, or who have poor knowledge of the purchase item tend to conduct a more extensive search. This was evident with our third cluster (Information Gatherers); several of these women were unknowledgeable about the supplement and/or information found on the label. They spent an average of 79 minutes shopping for the supplements compared with 40-45 minutes for individuals in the remaining clusters. The second level is referred to as "limited" problem solving. This type occurs when individuals are familiar with a particular product, but want to consider other unfamiliar brands in their decision. Women who typically shopped at the health food store were prime examples of this type of problem solver. And finally, the remaining level is referred to as "routinized." Those who have prior experience with a product as well as an available brand tend to exhibit this type of problem solving. Participants who habitually bought the same brand, or individuals who were familiar with the product because of past experience (e.g., recognition or loyalty) fell into this category.

Several of the participants used what is called, "surrogate quality indicators" (86). Individuals who were not familiar with a supplement or a product, or confused about the information on a label, who did not want to take the time to shop, or did not feel the

supplement was important, tended to use simplifying strategies to make their decisions. Several of the women became frustrated and confused with the evaluative process, and thus, limited their decision criteria to items or variables that were easy to identify with or were easy to use in evaluating the products, i.e., package color, price, brand, product description, and least number of ingredients. For example, one participant noted, "It would definitely be the price since I'm not interested in folic acid." Another commented, "I'm ignorant about it. I would, it would be hard for me to say; based on what I do with other things, I would choose the less expensive one, the most for the money." Many of these same criteria were used as tie-breakers when products were otherwise comparable.

Health Belief Model

The results obtained from the analysis of scores for the subscales of the Health Belief Model, indicate this sample of women were genuinely concerned with their health and the possibility of getting sick. In addition, they did not see taking a dietary supplement as a hindrance. With respect to the lower mean score derived for perceived susceptibility, a possible explanation may be the fact that this group of women were fairly young and relatively healthy, and may not have seen themselves at risk of developing the listed medical conditions. It is also important to point out that some of these individuals may have found dietary supplements beneficial against medical problems not mentioned as a response. For example, Blendon et al. (10) and Read et al. (24) found respondents believed that dietary supplements could help with colds, stress, skin problems, depression, anemia, and arthritis. For this study, higher mean scores were reported for the individual variables, osteoporosis and anemia. In this sample,

participants may have believed that diabetes, cancer, heart disease, and high blood pressure could be better treated with prescription medications versus dietary supplements. Results for cues to action and self-efficacy provide support to literature citing the reasons for dietary supplement use (10,21-24). The women in this sample were taking dietary supplements as a means to prevent illness, to compensate for a poor diet, or to enhance their overall health.

The standard deviations for all the subscales ranged from .64 to 1.01, indicating the women were responding similarly to questions with only a small variation in responses to the constructs. Thus, it was difficult to analyze beyond these findings. The Health Belief Model, however, remains a robust model for numerous studies looking at health related behaviors. With respect to those studies exploring breast cancer detection behavior, the results have been mixed. Some studies have found an association with only certain pieces of the model (112, 115,125), other studies have shown the complete model provides relatively strong predictive power (110,111,113), and for still other studies, the findings were inconsistent or insignificant (119, 124). The relative utility of the model with respect to dietary supplement use is still in question and is something that probably warrants further exploration. A contrast study that explores differences in beliefs among those who use dietary supplements compared to those who do not may be a better use of this model. And still, another model altogether may elicit results that prove more beneficial to explaining the beliefs, attitudes, and intentions associated with dietary supplement use.

Supplement Label

The final area examined in this study dealt with participants' knowledge and understanding of the information found on the supplement label. Three closed-ended questions and six open-ended questions were used. The majority of participants did well with information they could take directly from the supplement label. The questions that probed for responses, consisting of thoughts and concepts related to the individual's knowledge of terms and phrases found on the label, proved more troublesome. Several of the participants commented that they found some of the questions difficult to answer; others simply stated they did not know how to respond to the question; and still others stated they felt they had a fair understanding of the concept and felt comfortable providing an answer to the question.

The supplement facts label, implemented in 1999 under DSHEA, was intended to provide additional information to consumers to help them in evaluating products and thus enabling them to make better choices (53). The report of the President of the Commission on Dietary Supplement Labeling in 1997, included an appeal for research to determine whether consumers wanted information on the supplement label, and if so, could they appropriately use it to make decisions (1,29). This research begins to address and provide answers to the question.

Dose was one of the least understood pieces of information on the label. Several participants commented that they had no idea as to what the appropriate dose was for the supplement being looked at, or how much they should be taking. Some of the women indicated they would probably take a conservative approach, starting with a lower dose,

"to see how my body will react." For others, the preference was for a higher dose, using the mentality, "the higher, the better."

In terms of front label product claims, a few of the women remained skeptical and questioned the purported benefits. For a greater number of others, however, the claim served as an "attractant." The women were drawn to products that stated they could help with weight loss, would help with stress, or could improve an overall lack of energy.

Several of the women became frustrated with the evaluative process. For many of the participants, the terms and phrases found on the supplement label were a source of major confusion. Several of the women were unknowledgeable about the different types of ginseng; others were unable to figure out what "USP" or "standardized" meant. A few commented on the fact that they didn't understand how vitamin E could be "water soluble." Some of the women also reported that they had not realized there was no established daily value for herbals, and a few others had problems with knowledge of unit measures found on the label, such as micrograms and international units. Several of the women indicated they wished they had a better understanding of information on the supplement label, i.e., knowledge of added ingredients, appropriate dose measures, indications for use, and meanings of terms. A desire for more reliable information and guidance for supplement selection has been addressed in previous research (49).

Impact on Education

Individuals who lack adequate knowledge of the terms and information found on the supplement label, who do not know how to apply related concepts, and who rely on questionable sources for information on dietary supplements, are most likely unable to

make appropriate and informed decisions. The results of this study support the need for education. The quote by Jacoby (74) again illustrates the problem: "placing nutrition information onto a package label, we engage in printing, nothing more...we assume the act is equivalent to communicating with the consumer...assume or presuppose that the consumer wants, will acquire, and having acquired will understand and use the information." We simply cannot print information on a label and expect that consumers will understand and be able to utilize it in a manner that enables them to make adequate and informed decisions regarding supplement selection and use. This is a false assumption that may currently be held by both the government and health profession.

Implications for Health Educators

Results of the study strongly indicate the need for better guidance with respect to supplement selection, as well as education to help with comprehension and utilization of information pertaining to criteria used to purchase dietary supplements. Other research has also demonstrated this need (10,49). The opportunity for health educators to "step up to the plate" is clear. As health educators, it is important to be proactive and not wait for individuals to volunteer information on dietary supplement use. Studies indicate that greater than 50 percent of patients do not inform their physicians of the use of supplements (50-52). Educators need to initiate discussions with individuals about their use of dietary supplements and inquire about the concurrent consumption of prescription medications. Individuals believed to be at high risk for a potential herb/drug interaction include the elderly and seriously ill. Consumers should be advised to discuss the use of dietary supplements with their health care provider(s). Previous studies (9,10,49) have

shown that a large number of dietary supplement users are not consulting their physicians or other health care providers for advice on supplements, but instead are turning to health food store personnel, magazines, and family and friends. What is particularly concerning is the fact that many physicians, dietitians, and even pharmacists are uncomfortable discussing dietary supplements and have poor knowledge of indications for use, adverse effects, and current research findings, particularly when it comes to herbals (93,94,126). Thus, it is imperative that health educators take the initiative to become knowledgeable about dietary supplements and to stay informed of the changes and developments in research related to dietary supplements. Educators also need to remain open-minded with respect to the use of dietary supplements. It is important to provide individuals with sufficient and accurate information to use to make their own informed decisions regarding dietary supplements.

So where does one begin? As an educator, one of the first steps should be to determine what kind of decision-maker he/she is trying to educate. Questions to be addressed include: What are the factors that are influencing their choice of product? What do they consider salient criteria? What is motivating them to use dietary supplements? And finally, what does this person know with respect to the terms and information found on the supplement label? The answers to these questions impact education efforts, and inform the development of education programs that are more likely to target the specific needs of the intended receiver(s). Additionally, education initiatives should be individualized to the person, to effectively meet the needs of the individual.

Results of this study indicated the quality shopper tended to utilize more the primary value criteria (particularly price and quantity) and brand in deciding what supplements to purchase. Individuals in this cluster were concerned with getting a "quality" product. For this group, education efforts may be best targeted towards providing information credible or reliable manufacturers, questions to ask regarding product safety and testing, and information on how to identify products that have had some form of lab testing (e.g., USP/NF seal, standardized herbals). The bargain shopper relied heavily on primary value criteria in their purchase decision. For these individuals, an initial step to take would be to determine the reasons for dietary supplement use. Price, dose, and quantity may be being used as simplifying strategies to make supplement selection. If so, focus should be directed towards pointing out and discussing the additional criteria they may not be considering in their decision, and probably should be. For the information gatherers, these individuals were looking at and using criteria they did not always understand. For this group, an initial assessment should be done to determine the individual's level of knowledge pertaining to general terms and information found on the supplement label. Education initiatives can then be used to target areas of poor knowledge identified during the assessment.

Many individuals may also be taking supplements for reasons that are not medically based. In these cases, information can be provided to individuals with respect to those conditions for which dietary supplements may be warranted. Several vitamins and minerals have been shown to be beneficial to health in certain circumstances, however, for the herbals a lot of research is still needed before their use becomes

common practice. If individuals are taking herbal products to give them an "energy boost" or to make up for poor dietary habits, these needs may be better served by sharing tips and information on how to improve their dietary intake and improve their overall wellness. Some studies have indicated that those who take supplements probably do not need them, because of an intake high in fruits and vegetables, and incorporation of healthier eating practices (15,16,19,26). Guidance is needed to help individuals evaluate product claims, and definitions should be provided for some of the less understood terms found on the label, i.e., USP, standardized, and water-soluble. Individuals should be advised to take supplements according to the recommended dose on the label and not to exceed the upper limit for that nutrient. For herbals, the appropriate dose might not be known. In these cases, "bigger is not better" and consumers should be directed towards taking the lower doses. Individuals should also look for the USP/NF seal, as well as the word "standardized" when purchasing herbals. Sources for reliable and credible information on supplements and manufacturers should be provided, including recommended books and web sites. And finally, it is important that individuals understand that the word "natural" displayed on a label does not mean the supplement will not pose a health risk. Individuals may not be aware of current laws governing regulatory guidelines for dietary supplements. The proposed benefits, as well as the risks of using dietary supplements should be shared with consumers, regarding information related to the potential contamination of products, the potential risk for herb/drug interactions and hypersensitivity, as well as the questionable potency of supplements, particularly herbs. Individuals should be aware that there are no consistent measures for

ensuring safety with use of dietary supplements, and clinical trials within the United States to determine efficacy and safety with long-term use are limited.

While there is support for DSHEA, it is also recognized that there should be better regulatory guidance with respect to supplements placed on the market. The United States Pharmocopeia (USP) is working at this time to develop better standards for quality, purity, potency, and labeling for some of the more commonly consumed botanicals. The National Institutes of Health in collaboration with the Office of Dietary Supplements is supporting research to look at the efficacy of St Johns wort, saw palmetto, glucosamine/chondroitin, and gingko biloba (46). It has also been recommended that FDA adopt a rating system similar to the World Health Organization to help provide a distinction between those products that are considered relatively safe and beneficial to health against those items that may be potentially harmful with known adverse effects and/or are considered useless (29).

Limitations

Because this sample was considered a convenience sample, we cannot generalize the findings of the study to a broader population. The basic characteristics of our sample, however, represent the majority of women using dietary supplements, and as such, the researchers are fairly confident the results have applicability to women using dietary supplements. It should also be pointed out that while the intention was to create a realistic shopping experience, participants were being observed and were asked to shop for supplements that they may not have been familiar with. As a result, the participants may have paid more attention to details or may have taken more time in evaluating

products. In fact, some of the participants commented on how they noticed information on the supplement label that they had not noticed in the past. One of the women stated she felt she was spending more time looking at the products than she normally does during her shopping trips. The study did not address more closely the differences between regular use versus non-regular use of specific dietary supplements. In addition, women were only required to use one supplement at least four or more times weekly to be included in the study. As such, they may have been asked to artificially shop for supplements they did not regularly use. It is believed the strategies used to select these items may have been different from those strategies used for supplements regularly consumed.

The self-administered questionnaire was not tested for reliability or validity. In addition, there were minor problems noted with the inquiry about reported doses of currently consumed supplements. Some of the dose amounts were outside the normal range of what is found on products in drugstores or grocery stores; thus, data was considered unreliable and was not used for analyses.

The sample size for this study was intentionally kept small due to time constraints, and the nature of the research. As such, it is important to carefully consider this when interpreting the results of the study. With a larger sample size, the results for the number and type of variables and clusters may have been different. It is important to remember, however, that this research was intended to be exploratory in nature. The main purpose was not to test hypotheses, but rather to look for descriptive patterns, explore relationships among variables, and to generate more specific hypotheses for

future research. The results of this study provide a firm foundation upon which further testing can occur.

Future Research

It is suggested future research should focus on more diverse populations, specifically looking at gender, age, and demographic differences. Specific questions related to knowledge of use, safety issues, and potential adverse effects associated with herbals should also be included in assessments addressing knowledge. The Health Belief Model was believed to provide valuable insight into the beliefs and attitudes related to supplement use in this population. Results indicate, however, that the HBM may not be an appropriate model to use. Alternative models should be explored. Research that uses the Health Belief Model to look at contrast populations, i.e., regular use of dietary supplements versus non-use, or differences between males and females related to dietary supplement use might prove more beneficial. It is also the recommendation of this researcher that future studies be conducted within health food stores. It was reported as one of the most common places for purchase and source of information for supplements.

The most important finding from this research was the need for education. Individuals should be empowered in the decision-making process. Comprehensive programs that tailor to individual needs are needed before individuals can be expected to make reliable and informed decisions regarding supplement choice. Education initiatives that specifically address this need should be explored. A follow-up to this study includes the design and pilot testing of an education booklet to address the concerns and gaps in knowledge identified in this sample population.

CHAPTER VII

EPILOGUE

I first arrived at the University of North Carolina-Greensboro in the fall of 2000. The Air Force Institute of Technology (AFIT) had given me the opportunity to pursue a graduate degree. I was thrilled with the prospect of working with Dr. Carla Miller on the dietary supplement research project, but at the same time, I was a little apprehensive. It had been twelve years since I last sat in a classroom, and I knew things would be a little different this time around. However, since I had no previous experience with research, I really had no idea of what it all would entail. The opportunity to get a graduate degree, as well as participate in a "true" research study were primary reasons for applying for AFIT.

As I reflect over the past 20 months or so, I have to say the entire research process was an eye opening experience for me. I never realized all the steps involved from beginning to finish. The result, however, is the number of valuable experiences that I will carry with me after leaving UNCG. Juggling classes, my research project, and family was not easy. And being a graduate student was extremely time and effort dependent. In terms of research highlights, I'd have to say there were quite a few. First of all, I feel like I have a much better understanding of the research process, as well as a deeper appreciation for individuals who spend their lives doing research. Because of the nature of our research, I was able to learn a great deal about qualitative research,

specifically its value and purpose, as well as the statistics involved. Working with the study participants was also a highlight of the project. Their enthusiasm and willingness to share personal thoughts and opinions was greatly appreciated.

This thesis also afforded me the opportunity to learn a great deal about my research topic. I feel I have a better grasp of the regulatory guidelines that currently govern dietary supplements, as well as general information regarding issues related to quality assurance, safety, and efficacy of these products. The lack of FDA control over dietary supplements, however, is clearly evident. It is important that healthcare professionals (including myself) learn about dietary supplements and stay abreast of new developments and changes that occur with respect to supplements. We also need to take the initiative to begin education programs that will better meet the needs of consumers. My knowledge and understanding of consumer behavior has also broadened as a result of this research. I'd have to say the hardest part of the entire project was the writing and the coding of the transcripts. If I had it to do over again, I'd start my literature review a lot sooner. What I learned from working on these pieces, is that writing is something that does not come easy for me.

I found the shopping interviews very interesting; these women used a wide variety of strategies in working through the decision process. This research study was really an initial attempt at trying to identify those strategies or criteria influencing dietary supplement selection at point-of-purchase, or rather consumer purchase behaviors. This was also one of the first studies to look at consumer knowledge and understanding of terms and concepts found on the supplement label. The intent of using qualitative

research was to explore and identify specific patterns being used by these women with respect to the criteria used during the decision-making process. In addition, we wanted to determine knowledge and comprehension of terms and phrases associated with the supplement label.

Cluster analysis and factor analysis proved very useful when attempting to simplify data from the qualitative interviews. The type and frequency of use of the main criteria used across the sample helped to identify five distinct clusters of shoppers. I was asked whether I thought these women would move from one cluster to another given further education and improved knowledge. I have to believe that with improved knowledge many of these women would in fact move into a different cluster. Criteria previously ignored out of ignorance or because of poor knowledge could now play an important role as a determinant in supplement selection. Confounding factors, of course, would include changes in economic status and family needs. Humans are for the most part, inherently unpredictable; as such, what may hold true for one day may not necessarily hold true for the next. There are, however, exceptions, and these are those individuals who are "brand loyal" or brand conscious, who habitually select the same brand each time.

I'd have to say the most important finding, however, from this research is the clear need for education and better guidance with respect to supplement selection. What was particularly disturbing was the fact that these women, who were highly educated, had a poor understanding of many of the terms found on the supplement label, and knew very little about the regulatory process governing dietary supplements. There were many

occasions where participants became frustrated during the shopping experience, the result of confusion surrounding information on the supplement label.

All three areas of our research have a direct impact on education. Efforts really should be directed towards determining an individual's motivation for supplement use, assessing current knowledge and understanding of information on the supplement label, and identifying the salient criteria influencing the choice of a dietary supplement. This information is important to effectively tailor education messages to meet specific needs and interests of a target population. Multiple strategies may need to be employed; in addition, the message should be individualized to the individual. Until the regulatory process for dietary supplements changes, knowledge is our best weapon of defense to minimize the risk associated with dietary supplements.

If I had the opportunity to do the research again, what would I do differently? One thing I would alter, is the content of the questions used to assess knowledge of nutrients. The participants appeared to have a good general understanding of basic nutrients and food sources, and were fairly knowledgeable about vitamins and minerals, however, knowledge of herbals was considered poor. Specific questions that are directed at assessing knowledge of the safety and adverse effects of using herbals as well as implications for use should be included in future assessments. Second, if time and funding were not a concern, I would want to examine more closely consumer purchase behavior and the types of decision strategies used at point of purchase. A video camera in addition to an audio-tape would afford researchers the opportunity to observe more closely consumer behavior and strategies used to select dietary supplements.

It is the recommendation of this author that this research be carried forward. This study serves as an important stepping stone to further these results. A more quantitative based research model should be incorporated with more diverse populations, as well as an increase in the number of research subjects. Differences between males and females as well as differences in ethnicity and levels of income should be explored. In considering other populations, investigators may need to develop more creative recruitment strategies to capture the target audience. For instance, if looking at a low-income population, it may be necessary to focus recruitment strategies towards public health clinics, grocery stores, and discount pharmacies. Because of time and the nature of the research, our study was limited to 51 participants. With a larger sample size, it is expected that the number and type of variables as well as the type of clusters may change somewhat. Results from this study also indicate that the Health Belief Model may not be the best model to use for exploring and explaining individual beliefs and behaviors related to dietary supplement use. A different theoretical framework should be explored and may prove more beneficial with this type of research.

As a member of the active duty Air Force, I personally hope to carry forward with this research in an Air Force military population and continue exploring this worthwhile topic. Another initiative on my to do list includes the development of an outpatient education booklet to address identified concerns and problems associated with the supplement label. And on a final note, I 'd like to say how much I've enjoyed my time here at UNCG. I am extremely grateful to have worked with so many talented individuals. And I just want to say thank you.

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APPENDIX. FLYERS, FORMS, LETTERS, AND QUESTIONNAIRE

PROMOTIONAL FLYER FOR STUDY

Take Supplements?

THE UNIVERSITY OF NORTH CAROLINA

GREENSBORO

School of Human Environmental Sciences

Help us develop *better* educational programs for women about using dietary supplements such as vitamins, minerals and herbal products. We want to learn how women decide which supplements to purchase at the store. Women 25-45 years of age who take supplements on a weekly basis are welcome to participate. All you have to do is answer some general questions about supplements and complete one shopping interview.

Participants receive $20 for completing the study.

Please call **336-334-5081** for more information.

NEWSPAPER ADVERTISEMENT

TAKE SUPPLEMENTS?

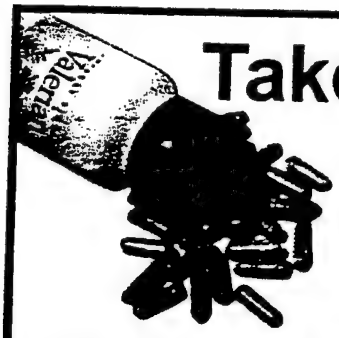
Join us for a dietary supplement study! Help us develop *better* educational programs for women about using vitamins, minerals and herbal products.

- Women 25-45 years of age who take supplements are welcome to participate.
- Participants receive $20 for completing the study.

This project is under the direction of Dr. Carla Miller at The University of North Carolina at Greensboro. Please call **256-0323** for more information.

Just For Women

DIETARY SUPPLEMENT STUDY at UNCG needs women 25-45 yrs old who take supplements. Participants need only to complete a 1-time shopping interview. Participants will receive $20 for completing the study. Info: 256-0323.



Take Supplements?

Join us for a dietary supplement study at UNCG! Help us develop *better* educational programs for women about using vitamins, minerals and herbal products.

- **Women 25-45 years of age who take supplements are welcome to participate.**
- **All you have to do is complete one shopping interview.**
- **Participants receive $20 for completing the study.**

This project is under the direction of Dr. Carla Miller at the University of North Carolina at Greensboro. Please call **(336) 256-0323** for more information.

TELEPHONE SCREENING INTERVIEW FORM

ID No._____

Subject's Name _____

Phone No. (H) _____-_____-_____ (W) _____-_____-_____

Call Completed ___/____/_____ Not Home _____/____/____

Call Back _____/_____/_____ at _____ am/pm

TELEPHONE SCREENING QUESTIONNAIRE

1. How did you learn of this study?

2. What is your gender? _____ female _____ male *If male, ineligible.*
3. Are you 25-45 years of age? _____yes _____no *If no, ineligible.*
4. Do you currently take any dietary supplements such as vitamins, minerals or herbal products? _____ yes _____no *If no, ineligible.*
5. Which supplements do you take on a regular basis?

   _____

   _____
6. How often do you take each supplement?

   _____

   _____

   If take < 1 supplement 4 times/week, ineligible.
7. Are you currently pregnant? _____ yes _____ no *If yes, ineligible.*
8. Are you trying to become pregnant? _____ yes _____ no *If yes, ineligible.*
9. Are you currently breastfeeding? _____ yes _____ no *If yes, ineligible.*
10. Do you currently have any medical conditions requiring treatment? ___ yes ___ no
If yes, please specify _____
11. What is your height? _____
12. What is your current weight? _____

END INTERVIEW QUESTIONS

Subject is _____ eligible _____ ineligible

* If ineligible, thank the person for their inquiry.
* If eligible, schedule appointment for shopping interview.

Date _____ Time _____ Forms mailed on _____

Address to mail forms:

_____

_____

_____

_____

COVER LETTER FOR PARTICIPANT PACKET

THE UNIVERSITY OF NORTH CAROLINA
GREENSBORO

School of Human Environmental Sciences

Dear Participant:

Thank you for participating in the Dietary Supplement Study. It was a pleasure to talk with you over the phone. We know many women take dietary supplements for health promotion. By talking with you, we learn the benefits you receive from taking supplements on a regular basis. The results of this program will be used to develop education programs for other women like you. Your contribution to the program will help us develop *better* education programs.

Two forms are attached to this letter. The first form is the "Consent to Act as a Human Subject" form. This form describes the purpose of the study. Please read the form and if you agree to continue in the study, sign it on the back page. The second form is a questionnaire about health issues for you to complete. It should take you about 20 minutes to read and complete both forms. Please complete them at your convenience before arriving at the shopping interview. Bring all completed forms with you to the interview. We look forward to seeing you there!

You are assured of complete confidentiality on all material and questionnaires. Your name will never be placed on any questionnaires. The forms have an identification number for mailing and matching purposes only. This is so we can coordinate the questionnaires with the people participating in the program. You will receive a $20 honorarium upon completion of the study as our way of thanking you for your time and contribution.

I will be happy to answer any questions you may have about the project. If you would like to speak to me, please call 336-334-5081. Thank you for being an important part of this project. Your contribution is valuable and makes this project possible!

Sincerely,

Carla Miller

Carla Miller, Ph.D.
Principal Investigator

318 Stone Building, UNCG, PO Box 26170, Greensboro, NC 27402-6170
(336) 334-5313 • FAX (336) 334-4129

INFORMED CONSENT LETTER

The University of North Carolina at Greensboro

CONSENT TO ACT AS A HUMAN SUBJECT
Long Form

Project Title: Knowledge and Use of Dietary Supplements among Women of Childbearing Age

Project Director: Carla Miller, Ph.D., Assistant Professor

Subject's Name: _____

Date of Consent: _____

DESCRIPTION AND EXPLANATION OF PROCEDURES:
The purpose of this study is to learn how women ages 25-45 years old feel about the benefits and risks of taking dietary supplements such as vitamins, minerals, and herbal preparations. We would like to understand how you decide which supplements to purchase while shopping. This information will help educators develop health education programs for other women in this age group. Please complete the enclosed written questionnaire. It will take you about 30 minutes to complete it. Then, a researcher will meet you at the store at the date and time we agreed upon for an individual shopping interview. While shopping, you will be asked to describe how you decide which dietary supplements to purchase and the factors that are important to you in the decision-making process. You will not have to actually purchase any of the supplements chosen.

RISKS AND DISCOMFORTS:
Participation in this research activity poses no serious physical, psychological or social harm to you. All of the information you give us will be identified by a code number rather than by your name. Your name will never be placed on any material. With your permission, the shopping interview will be recorded on audio tape. This will reduce the need to take notes and will save time during the interview. You may end your participation at any time. You may refuse to answer any questions on the questionnaire or during the interview.

POTENTIAL BENEFITS:
Most people find the shopping interview fun. There are no right or wrong answers during the interview. We simply want to learn how you decide which dietary supplements to purchase. The information will be used to develop educational programs for other women. You will receive a $20 honorarium for completing the study as our way of thanking you for your time and participation.

COMPENSATION/TREATMENT FOR INJURY:
I understand that, in the event of injury resulting from this investigation, neither financial compensation nor free medical treatment is provided for such an injury.

CONSENT:
By signing this consent form, I agree that I understand the procedures and any risks and benefits involved in this research. I am free to refuse to participate or to withdraw my consent to participate in this research at any time without penalty or prejudice; my participation is entirely voluntary. My privacy will be protected because I will not be identified by name as a participant in this project.

The research and this consent form have been approved by the University of North Carolina at Greensboro Institutional Review Board which insures that research involving people follows federal regulations. Questions regarding my right as a participant in this project can be answered by calling Dr. Beverly B. Maddox-Britt at (336) 334-5878. Questions regarding the research itself will be answered by Dr. Carla Miller by calling (336) 334-5081. Any new information that develops during the project will be provided to me if the information might affect my willingness to continue participation in the project.

By signing this form, I agree to participate in the project described to me by Dr. Carla Miller.

_____
Subject's Signature

_____
Witness to Signature

APPOINTMENT LETTER FOR SHOPPING INTERVIEW

Supplement Study
Appointment for Shopping Interview

You are scheduled for an interview at the drugstore at the following date and Time:

Date: _____

Time: _____

The interview will be done at the following location:

Kerr Drugstore
2190 Lawndale Drive
Greensboro
272-1453

Please call 334-5081 if you need to reschedule this interview. The interview will take about 1 hour. Remember to complete all of the questionnaires prior to the interview. We look forward to seeing you there!

Directions to Kerr Drugstore
If you are going north on Battleground Ave (I220 North), stay on Lawndale Dr. when Lawndale and Battleground split into two streets.
The drugstore is in the shopping center on the right side of the street after this split (Lawndale Shopping Center).
The store is at the corner of Lawndale Drive and Cornwallis Drive.

PARTICIPANT QUESTIONNAIRE

Supplement Study Questionnaire

This survey covers a variety of topics about dietary supplements and health. This information will help us develop better educational programs for women. We value your opinions. Your answers will be kept completely confidential. Please answer as honestly and accurately as you can. There are no right or wrong answers to most questions. Please select one answer to each question using the scale below for the first set of questions.

1 = not at all
2 = a fair amount
3 = a moderate amount
4 = a lot
5 = extremely

General Health Statements	**Not at all → Extremely**
1. How concerned are you about your health?	1 2 3 4 5
2. How concerned are you about the possibility of getting sick?	1 2 3 4 5
3. Taking all possible factors into consideration, do you think you have much of a chance of getting heart disease?	1 2 3 4 5
4. Taking all possible factors into consideration, do you think you have much of a chance of getting high blood pressure?	1 2 3 4 5
5. Taking all possible factors into consideration, do you think you have much of a chance of getting breast cancer?	1 2 3 4 5
6. Taking all possible factors into consideration, do you think you have much of a chance of getting diabetes?	1 2 3 4 5
7. Taking all possible factors into consideration, do you think you have much of a chance of getting osteoporosis?	1 2 3 4 5
8. Taking all possible factors into consideration, do you think you have much of a chance of getting anemia?	1 2 3 4 5

Severity of Illness	**Not at all → Extremely**
1. Suppose you were to get heart disease, how worried would you be about it?	1 2 3 4 5
2. Suppose you were to get high blood pressure, how worried would you be about it?	1 2 3 4 5
3. Suppose you were to get breast cancer, how worried would you be about it?	1 2 3 4 5

over please

4. Suppose you were to get diabetes, how worried would you be about it? 1 2 3 4 5
5. Suppose you were to get anemia, how worried would you be about it? 1 2 3 4 5

Medical Care **Not at all ⟶ Extremely**

1. How confident are you that doctors can cure heart disease? 1 2 3 4 5
2. How confident are you that doctors can cure high blood pressure? 1 2 3 4 5
3. How confident are you that doctors can cure breast cancer? 1 2 3 4 5
4. How confident are you that doctors can cure diabetes? 1 2 3 4 5
5. How confident are you that doctors can cure osteoporosis? 1 2 3 4 5
6. How confident are you that doctors can cure anemia? 1 2 3 4 5

Dietary Supplements **Not at all ⟶ Extremely**

1. How confident are you that dietary supplements can prevent you from getting heart disease? 1 2 3 4 5
2. How confident are you that dietary supplements can prevent you from getting high blood pressure? 1 2 3 4 5
3. How confident are you that dietary supplements can prevent you from getting breast cancer? 1 2 3 4 5
4. How confident are you that dietary supplements can prevent you from getting diabetes? 1 2 3 4 5
5. How confident are you that dietary supplements can prevent you from getting osteoporosis? 1 2 3 4 5
6. How confident are you that dietary supplements can prevent you from getting anemia? 1 2 3 4 5
7. How much do you feel taking a dietary supplement interferes with your normal activities? 1 2 3 4 5
8. How much do you feel taking a dietary supplement is costly? 1 2 3 4 5
9. How much do you feel taking a dietary supplement takes a lot of effort? 1 2 3 4 5

over please

We would like to ask you about the type of supplements you take. Please place a check mark in the column that best describes the supplements you take and how frequently you take each one. Then, write the dose of each supplement you take in the "Dose" column. For example, if you take 250 mg of vitamin C, write down "250 mg" for vitamin C. Please check the label on the supplement bottle for the dose that you take.

Vitamin Type	Number of Tablets						Dose		For How Many Years?				
Multiple Vitamins:	None	Less than once per week	1-3 per week	4-6 per week	1 per day	2+ per day			Less than 1 year	1-2 yr	3-5 yr	6-9 yr	10+ yr
One-a-day type							XXXXX						
Stress-tab type							XXXXX						
Therapeutic Theragran-type							XXXXX						
Other Vitamins:													
Vitamin A													
B-complex													
Vitamin C													
Vitamin D													
Vitamin E													
Folic acid													
Minerals:													
Calcium													
Chromium picolinate													
Iron													
Magnesium													
Selenium													
Zinc													

over please

Others	Number of Tablets						Dose		For How Many Years?				
Other Products:	None	Less than once per week	1-3 per week	4-6 per week	1 per day	2+ per day			Less than 1 year	1-2 yr	3-5 yr	6-9 yr	10+ yr
Alfalfa													
Amino acids													
Echinacea													
Lecithin													
Melatonin													
Protein powder													
St. John's Wort													
Garlic													
Ginkgo biloba													
Ginseng													
Valerian root													

1. If you take vitamin C, do you take it only when you suspect the beginning of a cold?
   ____ No, I take it regularly
   ____ Yes, I take it only when I have symptoms of a cold

2. Are there any other supplements besides the ones listed in the table above that you take on a regular basis?
   ____ No
   ____ Yes, please specify the type and amount of the supplement(s) and how long you have been taking this supplement in the space below.

Type of Supplement:	Dose:	For how long?
_____	_____	_____
_____	_____	_____
_____	_____	_____

over please

3. How confident are you that you can receive an adequate amount of the vitamins and minerals your body needs from only the foods you eat?
   _____ extremely confident
   _____ very confident
   _____ somewhat confident
   _____ slightly confident
   _____ not at all confident

4. What caused you to start taking dietary supplements? Please check all that apply.
   _____ an illness
   _____ my desire to prevent an illness
   _____ a feeling of lack of energy
   _____ a family member or friend recommended I take a supplement
   _____ an advertisement about supplements
   _____ other, please describe _____

5. Where do you receive information about dietary supplements? Please check all that apply.
   _____ health food store
   _____ television
   _____ radio
   _____ magazine
   _____ health book
   _____ friends
   _____ family
   _____ co-workers
   _____ physician
   _____ dietitian or nutritionist
   _____ other health care professional, please describe _____
   _____ other, please describe _____

6. Where do you usually purchase dietary supplements? Please check all that apply.
   _____ grocery store
   _____ drugstore or pharmacy
   _____ health food store
   _____ mail order
   _____ direct sales
   _____ other, please describe _____

7. How frequently do you visit a health food store? Please check one.
   _____ 1 or more times per week
   _____ 1-3 times a month
   _____ less than 1 time per month
   _____ never

over please

8. Is your personal physician aware of the dietary supplements you take?
   _____ yes
   _____ no

9. Has a physician ever recommended you take a dietary supplement?
   _____ yes For what condition? _____
   _____ no

10. Do other members of your household take a dietary supplement? Please check all that apply.
   _____ spouse or partner
   _____ children
   _____ parent
   _____ other family member
   _____ non family member
   _____ I'm the only one who takes a supplement in my household.

11. On average, how much do you spend per month on dietary supplements?
   _____ $0 - $10
   _____ $11 - $20
   _____ $21 - $30
   _____ $31 - $40
   _____ More than $40

Please circle one answer for each of the following questions. If you do not know an answer, please circle "don't know." This information will help us know the type of information to include about dietary supplements in the educational material we develop for women.

1. Which of the following foods is highest in vitamin A?
   A. **Spinach**
   B. Salmon 52% correct
   C. Pears
   D. Potato
   E. Don't Know

2. Which of the following foods is highest in vitamin D?
   A. Chicken
   B. Whole-grain cereals
   C. Yellow squash
   D. **Milk** 84% correct
   E. Don't Know

over please

3. Which of the following foods is highest in vitamin E?
   A. Orange
   B. Broccoli
   C. **Corn Oil** 34% correct
   D. Steak
   E. Don't Know

4. Which of the following foods is highest in vitamin C?
   A. **Grapefruit** 90% correct
   B. Watermelon
   C. Banana
   D. Apple
   E. Don't Know

5. Which of the following foods is highest in calcium?
   A. Breakfast cereal
   B. **Cheese** 90% correct
   C. Carrots
   D. Pork
   E. Don't Know

6. If you wanted to add significant quantities of vitamins and minerals to your diet from the food you eat, a good choice would be:
   A. Bread made with enriched white flour
   B. A fortified breakfast cereal 84% correct
   C. Skim milk
   D. Apple juice
   E. Don't Know

7. Women who use an oral contraceptive may need to take which of the following supplements?
   A. Thiamin
   B. Niacin
   C. Vitamin B6 30% correct
   D. Echinacea
   E. Don't know

8. Women who are trying to become pregnant may need to take which of the following supplements?
   A. Ginseng
   B. Vitamin E
   C. **Folic Acid** 71% correct
   D. Vitamin B12
   E. Don't know

over please

9. Women who are anemic may need to take which of the following supplements?
   A. Vitamin K
   B. Iron 96% correct
   C. Niacin
   D. Vitamin A
   E. Don't know

10. Which of the following supplements is an antioxidant?
   A. Magnesium
   B. Zinc
   C. Calcium
   D. Vitamin E 70% correct
   E. Don't know

To finish things off, we would like to ask you some general questions about yourself to help us interpret the results of the study.

1. In general, would you say your health is (please check one):
   _____ excellent
   _____ very good
   _____ good
   _____ fair
   _____ poor

2. Do you currently have any of the following conditions?

	Yes	**No**
Heart Disease	____	____
High blood pressure	____	____
Breast cancer	____	____
Other types of cancer	____	____
Diabetes	____	____
Osteoporosis	____	____
Anemia	____	____
Kidney Disease	____	____
Chronic Pain	____	____

3. Do you have any other medical condition?
   _____ yes Please specify _____
   _____ no

4. Do you exercise on a regular basis?
   _____ yes
   _____ no (please skip to question 6)

over please

5. How often do you exercise?
   _____ 6-7 times per week
   _____ 3-5 times per week
   _____ 1-2 times per week
   _____ less than 1 time per week

6. What is your year of birth? 19_____

7. Please check your education level.
   _____ Less than 12th grade
   _____ High school diploma or GED
   _____ Some college
   _____ Bachelor's Degree
   _____ Advanced Degree (M.S., Ph.D., M.D.)

8. What is your employment status?
   _____ Full-time (32 hours or more per week)
   _____ Part-time (less than 32 hours per week)
   _____ Full-time student
   _____ Full-time homemaker
   _____ Unemployed
   _____ Retired

9. What is your race?
   _____ White
   _____ African-American
   _____ Asian-American
   _____ Native-American
   _____ Hispanic-American
   _____ Other, please specify _____

10. Who currently lives with you in your household?
   _____ Live with spouse only
   _____ Live with children only
   _____ Live with spouse and children
   _____ Live with someone other than spouse or children
   _____ Live alone

11. Which of the following best describes your household income in 1999?
   _____ Less than $10,000
   _____ $10,000 to $19,999
   _____ $20,000 to $29,999
   _____ $30,000 to $39,999
   _____ $40,000 to $49,999
   _____ $50,000 to $59,999
   _____ $60,000 or more

over please

13. What is the best way for you to learn new information?

_____

_____

_____

Your contribution to the study is greatly appreciated. **Remember to bring this questionnaire with you to the interview.** We look forward to seeing you there!

DIETARY SUPPLEMENT SHOPPING LIST

ID NO. _____
Start time _____
Stop time _____
Time to complete interview _____

Supplement Shopping List

Pease choose one of each of the following supplements and place the item in the shopping basket. Check if the supplement is something you take regularly (at least monthly) or less regularly (less than once per month or never).

Supplement	Take regularly	Don't take regularly
Calcium		
Chromium Picolinate		
Folic acid		
Multivitamin plus iron		
Selenium		
Vitamin C		
Vitamin E		
Echinacea		
Gingko Biloba		
Ginseng		
St Johns wort		
Valerian root		

POST INTERVIEW SUMMARY SHEET

ID NO. _____

Dietary Supplement Study
Post Interview Notes

Factors which affect this person's decision-making for supplements:

Other comments:

RECEIPT FORM

Dietary Supplement Study

This acknowledges receipt of $20.00 for participating in the Dietary Supplement Study. This study was conducted through the Department of Nutrition under the direction of Dr. Carla Miller at the University of North Carolina at Greensboro.

_____

Signature

_____

Date

CODE DEFINITION SHEET

CODE DEFINITIONS FOR FACTORS AFFECTING SUPPLEMENT SELECTION AT POINT OF PURCHASE

- **Product Function/Use/Description (PFU):** recommended use for the product; information provided on package/label describing specific function(s) or description of the product
- **Package Color/Graphics (PCG):** blend or mix of colors on package; package graphics or overall package appearance
- **Packaging Attributes/Marketing (PA):** shape or size of supplement container or bottle; labeling characteristics, "twist-n-learn" marketing,
- **Price ($):** total cost of the product, affected by brand and quantity per container
- **Absorption/Digestion (AD):** how well the product is digested and absorbed by the body
- **Brand Name/Trust/Familiarity (BN):** association of product quality and safety with name; trust in company; familiarity with product/name (used the product or knows someone who has used or is using the product)
- **Generic (GN):** preference for store brand over name brand (belief product is equally comparable to name brand)
- **Dose Frequency/Dose Instructions (DF):** how often the product is taken; recommended instructions for taking the supplement, i.e serving size or number of pills to take
- **Dose Measure**:
  - **Dose Amount per Unit (DAU):** dose amount of the product per pill, tablet, soft gel, etc.
  - **Low/Moderate Dose (LMD):** dose is at a low/moderate level in terms of total mg/mcg/gm of the supplement
  - **100% DV or Higher Dose (%DV/HD):** dose is at 100% DV or higher for the recommended mg/mcg/gm of the supplement; prefers higher dose
  - **%DV (%DV):** a unit of measure; general %DV provided
- **Quality:**
  - **Standardized/USP (SD):** indicator of quality; product consistency in terms of manufacturer using the same ingredients, same dose, etc during production; product testing
  - **Expiration Date (ED):** when a product is no longer recommended for sale
  - **Guarantee (GUA):** indicator of quality; often found on product label (100% guarantee)
- **No additives/preservatives/colorings (NAP):** product is free of additives as well as added colorings or preservatives
- **Natural Source of Nutrient/Herb (NAT):** label contains statement product is made from a "natural source" or states product is "100% natural"

Code Definitions continued:

- **Ingredients (ING):** general term to indicate all ingredients in a product as a "whole"
- **Order of Ingredients (OOI):** the order in which the ingredients present/appear on the label
- **Multi-Supplement Blends (MSB):** nutrients or herbs are added to the product which may enhance the function of the product; complex or multi-supplement formulations (in general)
- **Specific Mix/Blend of Nutrients/Herbs (MNH):** product contains a specific mix or blend of nutrients/herbs in a supplement the consumer is looking for
- **Nutrient/Herb Source (NHS):** form or source of nutrient/herb
- **Amount of Added Ingredients (AI):** number of ingredients added to a supplement (in addition to the main nutrient/herb) i.e. sugar, salt, lecithin, soybean oil
- **Type of Support Ingredients (TSI):** the different support ingredients added to the main nutrient/herb in a supplement
- **Size of Pill/Tablet (SOP):** size of pill or tablet (some individuals prefer small pills)

- **Supplement Form**:
  Soft Gel (SG): a supplement form, often easier to swallow; soft material filled with liquid
  Chewable (CHEW): a supplement form; product is chewed vs swallowed
  Tablet/Caplet/Pill (TCP) : most common form; hard to swallow at times
  Tincture/Liquid (TNC): liquid form of a supplement; as a tincture drops are added to another liquid or water
  Time Released (TR): product is released in the body over a specified period of time, i.e., 4-6 hrs

- **Quantity of Product (QP):** the quantity of pills/tablets/gels in a container

- **Small # Unit per Container (SUPC):** a smaller number of pills/tablets/gels etc. per container

- **Value Container (VC):** greater number of pills/tablets/gels per container; may be considered a "value" based on the number of units per total cost of product

- **Perceived Health Benefit (PHB):** perceived individual health benefit from taking the supplement

- **Family Member Benefit (FMB):** belief that a family member will benefit from taking the supplement

- **Other: Taste/Flavor (TF):** product tastes good or has a pleasant flavor

Other:

Other:

Other:

Other:

Other:

Other:

MULTIVITAMIN

ALL FACTORS CONSIDERED FOR DIETARY SUPPLEMENT SELECTION AT POINT OF PURCHASE

VARIABLES	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	26	27
Product Function/Use																									
Pkg Color/Graphic/Appearance																									
Pkging Attributes/Marketing																									
Price																									
Absorption/Digestion																									
Brand Name/Trust/Familiarity																									
Generic																									
Dose Frequency/Dose Instrctns																									
Dose Measure																									
Dose Amount per Unit																									
Low/Moderate Dose																									
100% DV or Higher Dose																									
% DV																									
Quality																									
"Standardized" /USP																									
Expiration Date																									
Guarantee																									
No additives/preserv/colorings																									
Natural Source Nutrient/Herb																									
Ingredients (as a whole)																									
Order of Ingredients																									
Complimentary Nutrients																									
Mix of Nutrients/Herbs																									
Nutrient/Herb Source																									
Amount of Added Ingredts																									
Type of Added Ingredts																									
Size of Pill/Tablet																									
Supplement Form																									
Soft Gel																									
Chewable																									
Tablet/Caplet																									
Tincture/Liquid																									
Time Released																									
Qty of Product (i.e. # pills)																									
Small # Unit Per Container																									
Value Container																									
Perceived Health Benefit																									
Family Member Benefit																									
Other:																									
Other:																									
Other:																									

CALCIUM

FACTORS/VARIABLES CONSIDERED FOR DIETARY SUPPLEMENT SELECTION AT POINT OF PURCHASE
(15 December 01)

VARIABLES	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	26	27	28
Non-Nutritn Related Info																										
Pkg Attributes																										
Dose Freq/Instructions																										
Narrative Wording																										
Dose																										
Price/Value Container																										
Brand Name/Generic																										
Quality (Purity/Potency)																										
Absorpn/Dig & Time Rel																										
Natl, NAP, A/T Supp Ing																										
Ingred/Nutrient Herb Src																										
Pkg Form(SS/MS Blend) & Specific Mix																										
Supplement Form																										
Quantity of Product																										